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Paper 109  
Filed: 29 September 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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HARUO **SUGANO**,  
MASAMI MURAMATSU, and TADATSUGU TANIGUCHI

Junior Party  
(Patent 5,514,567 and 5,326,859),

v.

DAVID V. **GOEDEL**,  
and ROBERTO CREA

Senior Party  
(Application 07/374,311).

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Patent Interference No. 105,334)  
(Technology Center 1600)

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*Before:* RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P.  
TIERNEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

**Decision – Motions – Bd.R. 125(a)**

1   **I. Introduction**

2           Related interferences 105,334 ('334) and 105,337 ('337) were declared on  
3   25 August 2006. ('334 and '337 at Paper 1). Both parties have filed non-priority  
4   motions.

5           Oral argument on the non-priority motions was held on 10 October 2007.  
6   ('334 at Paper 105 and '337 at Paper 108). Thomas Friebe argued on behalf of  
7   Goeddel and Nels Lippert argued on behalf of Sugano.

8   **II. Background**

9           The subject matter of interference 105,334 is DNA coding for human  
10   fibroblast  $\beta_1$  interferon (hFIF). The subject matter of interference 105,337 is the  
11   polypeptide hFIF..

12          The parties agree that the "precursor form" of hFIF is a 187 amino acid  
13   protein containing a 21 amino acid "presequence" that is attached to the amino  
14   terminus of the 166 amino acid "mature" form of hFIF. The parties further agree  
15   that the first thirteen amino-terminal amino acids of the mature form of hFIF were  
16   known in the art as of February 1980. The parties also agree that the Count of  
17   each interference should be limited to either the mature form of hFIF, i.e., the 166  
18   amino acid mature form that lacks the 21 amino acid "presequence" ('337) or the  
19   DNA encoding the mature form of hFIF ('334). It appears that, a previous  
20   interference, i.e., interference 101,096, dealt with the issue of priority as to the  
21   precursor form of hFIF.

1           In interference 105,334, Goeddel has filed eight substantive motions.  
2       Seven of these motions are motions for judgment that the Sugano claims are  
3       unpatentable over prior art or under 35 USC §101 and §112. One of these seven  
4       motions is a motion for judgment that the Sugano claims are unpatentable for  
5       failure to comply with the written description requirement of 35 USC §112, ¶1,  
6       and another is a motion for judgment that the Sugano claims are unpatentable for  
7       failure to comply with the enablement requirement of 35 USC §112, ¶1. Goeddel  
8       also has filed a motion seeking to substitute proposed Count 2 for Count 1.

9           We deny each of the Goeddel motions for judgment that the Sugano  
10       claims are unpatentable for failing to comply with the written description or  
11       enablement requirement. We grant the Goeddel motion to substitute a Count.  
12       We dismiss the other Goeddel motions.

13           In interference 105,337, Goeddel has filed seven substantive motions. Six  
14       of these motions are motions for judgment that the Sugano claims are  
15       unpatentable over prior art or under 35 USC §101 and §112. One of these six  
16       motions is a motion for judgment that the Sugano claims are unpatentable for  
17       failure to comply with the written description requirement of 35 USC §112, ¶1,  
18       and another is a motion for judgment that the Sugano claims are unpatentable for  
19       failure to comply with the enablement requirement of 35 USC § 112, ¶1.  
20       Goeddel also has filed a motion seeking to substitute proposed Count 2 for  
21       Count 1.

22           Key issues in the Goeddel motions we have considered are (1) whether  
23       Goeddel has shown that the current Count in each interference encompasses

1 more than the DNA coding for ('334), or the polypeptide having ('337), the amino  
2 acid sequence of mature hFIF; (2) whether Goeddel has shown that Sugano did  
3 not have possession of the DNA coding for, or the polypeptide having, the amino  
4 acid sequence of mature hFIF , and (3) whether Goeddel has shown that at the  
5 time of the filings of the applications underlying the involved Sugano patents  
6 ('334) and involved Sugano application ('337), one skilled in the art would not  
7 have been able to make and use the DNA coding for, and the polypeptide  
8 having, the amino acid sequence of mature hFIF. We determine that the current  
9 Counts do encompass more than is properly the subject matter of each  
10 interference and thus grant the Goeddel motions to substitute a Count. Goeddel  
11 has not shown that Sugano failed to provide written description and enablement  
12 for the claimed subject matter and deny the Goeddel motions seeking judgment  
13 against Sugano on those bases. All other Goeddel motions are dismissed.

14 In each interference, Sugano has filed four substantive motions, three of  
15 which have been deferred. The single Sugano motion presently before us is a  
16 motion seeking priority benefit of Sugano Japanese patent application no.  
17 33931/1980 filed 19 March 1980. ('931 JP application).

18 The key issue in the single Sugano motion that is before us in each  
19 interference, is whether, in its '931 JP application, Sugano provided sufficient  
20 description of, and enabling disclosure for, the mature form of hFIF and the DNA  
21 coding for the mature form. We have determined that Sugano has provided  
22 written description and enablement for the mature form of hFIF, and the DNA

1 coding for the mature form of hFIF, in the '931 JP application. We grant the  
2 Sugano motions for benefit. All other Sugano motions are dismissed.

3 Because Sugano has established an earlier constructive reduction to  
4 practice in its '931 JP application, we have determined that Sugano is entitled to  
5 priority benefit of that application. Goeddel has not alleged a date in its priority  
6 statement that is prior to the filing date of the '931 JP application. Accordingly,  
7 Goeddel cannot prevail in the interference and judgment shall be entered against  
8 Goeddel in a separate paper.

9 Interference 105,334

10 In interference 105,334, Goeddel filed the following motions:

11 1. A motion to substitute proposed Count 2 for Count 1 (Paper 27).

12 Sugano opposed. (Paper 57).

13 2. A motion for judgment that the Sugano claims are unpatentable  
14 under 35 USC §101 in view of the human chromosome. (Paper 28). Sugano  
15 opposed. (Paper 58).

16 3. Three motions for judgment that the Sugano claims are  
17 unpatentable over prior art (Papers 29-31), two of which have been deferred.  
18 (Paper 54). Sugano opposed as to the non-deferred motion. (Paper 59).

19 4. A motion for judgment that the Sugano claims lack enablement  
20 under 35 USC §112, ¶1. (Paper 32). Sugano opposed. (Paper 60).

21 5. A motion for judgment that the Sugano claims lack written  
22 description under 35 USC §112, ¶1. (Paper 33). Sugano opposed. (Paper 61).

6. A motion for judgment that the Sugano claims are unpatentable for lack of utility under 35 USC §101 and §112, ¶1. (Paper 34). Sugano opposed. (Paper 62).

7. A motion to exclude certain evidence relied upon by Sugano. (Paper 82). Sugano opposed. (Paper 90).

Sugano filed the following motions.

1. Two motions for judgment that the Goeddel claims are unpatentable over prior art. (Paper 36 and 37). Both motions have been deferred. (Paper 54).

2. A motion for judgment that the Goeddel claims are unpatentable under 35 USC §102(f). (Paper 38). This motion has been deferred. (Paper 47).<sup>1</sup>

3. A motion to be accorded priority benefit of an earlier filed application. (Paper 39). Goeddel opposed. (Paper 55).

4. A motion to exclude certain evidence relied upon by Goeddel in certain Goeddel replies. (Paper 86). Goeddel opposed. (Paper 89).

Interference 105,337

In interference 105,337, Goeddel filed the following motions:

1. A motion to substitute proposed Count 2 for Count 1 (Paper 39).  
Sugano opposed. (Paper 63).

1 A motion based on third party derivation was authorized to be filed during the non-priority phase of the interference. Because the motion filed by Sugano was not based on third party derivation but alleged derivation from Sugano, further briefing was deferred. (Paper 47 at 3). Since judgment will be entered against Goeddel, the issue of derivation is moot.

1           2.     A motion for judgment that the Sugano claims are unpatentable  
2     under 35 USC §101 in view of the human chromosome. (Paper 40). Sugano  
3     opposed. (Paper 64).

4           3.     Two motions for judgment that the Sugano claims are unpatentable  
5     over prior art. (Papers 41 and 42), both of which have been deferred.  
6     (Paper 60).

7           4.     A motion for judgment that the Sugano claims lack enablement  
8     under 35 USC §112, ¶1. (Paper 43). Sugano opposed. (Paper 65).

9           5.     A motion for judgment that the Sugano claims lack written  
10    description under 35 USC §112, ¶1. (Paper 44). Sugano opposed. (Paper 66).

11          6.     A motion for judgment that the Sugano claims are unpatentable for  
12    lack of utility under 35 USC §101 and §112, ¶1. (Paper 45). Sugano opposed.  
13    (Paper 67).

14          7.     A motion to exclude certain evidence relied upon by Sugano.  
15    (Paper 85). Sugano opposed. (Paper 94).

16               Sugano filed the following motions.

17          1.     Two motions for judgment that the Goeddel claims are  
18    unpatentable over prior art. (Paper 32 and 33). Both motions have been  
19    deferred. (Paper 60).

20          2.     A motion for judgment that the Goeddel claims are unpatentable  
21    under 35 USC §102(f). (Paper 34). This motion has been deferred. (Paper 51).<sup>2</sup>

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<sup>2</sup>     A motion based on third party derivation was authorized to be filed during the non-priority phase of the interference. Because the motion filed by Sugano was not based on third party derivation but alleged derivation from Sugano,

1           3.     A motion to be accorded priority benefit of an earlier filed  
2 application. (Paper 32). Goeddel opposed. (Paper 61).

3           4.     A motion to exclude certain evidence relied upon by Goeddel in  
4 certain Goeddel replies. (Paper 89). Goeddel opposed. (Paper 92).

5     **III.     Findings of fact**

6           The record supports the following findings of fact by a preponderance of  
7 the evidence.

8                                     Interference 105,334

9           1. Interference 105,334 was declared on 25 August 2006. (Declaration,  
10 Paper 1).

11          2. Sugano is involved in interference 105,334 on the basis of the following  
12 two patents:

13           5,514,567, issued on 7 May 1996 from application  
14 08/400,179, filed 6 March 1995

15  
16           5,326,859, issued on 5 July 1994 from application  
17 06/201,359, filed 27 October 1980

18  
19     (*Id. at 3*).

20  
21          3. The inventors in each patent are said to be Haruo Sugano, Masami  
22 Muramatsu, and Tadatsugu Taniguchi.

23          4. Sugano has identified the real parties in interest as “Judicial Foundation,  
24 Japanese Foundation for Cancer Research,” said to be an assignee, and

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further briefing was deferred. (Paper 51 at 3). Since judgment will be entered against Goeddel, the issue of derivation is moot.



1           “Kyowa Hakko Kogyo Co., Ltd.,” “Toray Industries, Inc., and “Schering  
2           Aktiengesellschaft,” said to be licensees. (Paper 6).

3           5. Goeddel is involved in the interference on the basis of its application  
4           07/374,311, filed 30 June 1989. (Paper 1 at 4).

5           6. The inventors in the application are said to be David V. Goeddel and  
6           Roberto Crea.

7           7. Goeddel has identified the real party in interest as Genentech, Inc. (‘334  
8           at Paper 11).

9           8. The count of the interference, Count 1, is as follows:

10                               Claim 9 of Sugano, 5,514,567

11   or

12                               claim 6 of Sugano, 5,326,859

13   or

14                               claim 35 of Goeddel, 07/374,31

15           (Paper 1 at 4).

16           9. Claim 9 of Sugano patent 5,514,567 (‘567) is as follows:

17           A recombinant plasmid wherein a DNA which codes for the amino  
18           acid sequence:

19

20           Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
21           Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
22           Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu  
23           Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
24           Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
25           Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
26           Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe  
27           Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
28           Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
29           Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
30           Leu Thr Gly Tyr Leu Arg Asn

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is inserted in a vector DNA.

(Sugano clean copy of claims, Paper 5).

10. Claim 6 of Sugano patent 5,326,859 ('859) is as follows:

A DNA consisting essentially of a DNA which codes for mature human fibroblast interferon polypeptide having the amino acid sequence:

Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe Gln  
Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys Leu  
Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu Gln  
Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu Gln  
Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp Asn  
Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile Asn  
His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe Thr  
Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly Arg  
Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp Thr  
Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg Leu  
Thr Gly Tyr Leu Arg Asn.

(*Id.*).

11. Claim 35 of Goeddel application 07/374,311 is as follows:

A DNA consisting essentially of a DNA which codes for mature human fibroblast interferon polypeptide having the amino acid sequence:

Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu  
Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe  
Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
Leu Thr Gly Tyr Leu Arg Asn.

(Goeddel clean copy of claims, Paper 9).

1 12. The parties were accorded the following benefit for Count 1:

2 Sugano:

3 US 06/389,922, filed 18 June 1982

4 US 06/201,359, filed 27 October 1980, issued as involved  
5 patent 5,326,859 on 5 July 1994<sup>3</sup>

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9 Goeddel:

10 US 06/879,712, filed 27 June 1986

11 US 06/291,892, filed 11 August 1981

12 US 06/190,799, filed 25 September 1980

13 (Paper 1 at 5).

14 13. Claims 9-14, 18-20, 24-27, and 29 of Sugano's '567 patent, claims 1 and

15 6-9 of Sugano's '859 patent and claims 25-52 of Goeddel's involved

16 application, are designated as corresponding to Count 1. (*Id.*).

17 14. According to Goeddel's priority statement (Bd. R. 204 (a)(2)), as to the

18 subject matter of Count 1, "Party Goeddel's earliest corroborated

19 conception was in the United States on May 7, 1980". (Paper 25).

20 Interference 105,337

21 15. The interference was declared on 25 August 2006. (Declaration, Paper 1).

22 16. Sugano is involved in interference 105,337 on the basis of its application

23 08/463,757, filed 5 June 1995. (*Id. at 3*).

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<sup>3</sup> In application 06/201,359, Sugano claimed a priority date of 19 March 1980 based on the '931 JP application. 35 USC §119(a). (Inventor declaration in Exh. 2009). Sugano was not accorded benefit of the '931 JP application in the Declaration of Interference.

1 17. The inventors in the application are said to be Haruo Sugano, Masami  
2 Muramatsu, and Tadatsugu Taniguchi.

3 18. Sugano has identified the real parties in interest as “Judicial Foundation,  
4 Japanese Foundation for Cancer Research,” said to be an assignee, and  
5 “Kyowa Hakko Kogyo Co., Ltd.,” “Toray Industries, Inc.,” and “Schering  
6 Aktiengesellschaft,” said to be licensees. (Paper 6).

7 19. Goeddel is involved in the interference on the basis of its patent  
8 5,460,811, issued on 24 October 1995 from application 07/365,284, filed  
9 12 June 1989.

10 20. The Goeddel inventors are said to be David V. Goeddel and Roberto  
11 Crea.

12 21. Goeddel has identified the real party in interest as Genentech, Inc. (Paper  
13 13).

14 22. The count of the interference, Count 1, is as follows:

15  
16 Claim 31 of Sugano, 08/463,757  
17  
18 or  
19  
20 claim 2 of Goeddel, 5,460,811.  
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22 (Paper 1 at 4).

23 23. Claim 31 of application 08/463,757 is as follows:

24 Recombinant human fibroblast  $\beta$ 1 interferon having the  
25 amino acid sequence:  
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27 Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
28 Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
29 Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu

Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe  
Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
Leu Thr Gly Tyr Leu Arg Asn.

( Sugano clean copy of claims, Paper 5).

24. Claim 1 (from which claim 2 depends) and claim 2 of Goeddel 5,460,811  
are as follows:

(claim 1) A composition comprising water and a  
nonglycosylated polypeptide having the amino acid sequence of a  
mature human fibroblast interferon, said nonglycosylated  
polypeptide having a total of 165 or 166 amino acids and said  
composition being free of any glycosylated human fibroblast  
interferon.

(claim 2)The composition of claim 1, said nonglycosylated  
polypeptide having the amino acid sequence

X-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-  
Gln- Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-  
Cys-Leu- Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-  
Gln-Leu-Gln- Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-  
Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-  
Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-  
Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-  
Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-  
Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-  
Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-  
Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn,

wherein X is H or Met.

(Goeddel clean copy of claims, Paper 10).

25. The parties were accorded the following priority benefit as to Count 1:

1 Sugano:  
2  
3 US 08/400,179, filed 6 March 1995,  
4 issued as 5,514,567 on 7 May 1996  
5  
6 US 06/389,922, filed 18 June 1982  
  
7 US 06/201,359, filed 27 October 1980,  
8 Issued as 5,326,859 of 5 July 1994<sup>4</sup>  
9

10 Goeddel:  
11 US 06/889,722, filed 28 July 1986  
12 US 06/291,892, filed 11 August 1981  
13 US 06/190,799, filed 25 September 1980

14 (Paper 1 at 4-5).

15 26. Sugano claims 4, 30, 31, 36, 39-44, 46, and 48-50 and Goeddel  
16 claims 1-6 were designated as corresponding to Count 1. (Paper 1 at 4).  
17 27. According to Goeddel's priority statement (Bd. R. 204 (a)(2)), as to the  
18 subject matter of Count 1, "Party Goeddel's earliest corroborated  
19 conception was in the United States on May 7, 1980". (Paper 30).

20 Substitute Count

21 28. The parties agree that the Count in each interference should be limited to  
22 DNA encoding or the polypeptide having only the 166 amino acids of  
23 mature hFIF. (Transcript, '334, Paper 108 and '337, Paper 111 at 7:11-15  
24 and 32:1-7).

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<sup>4</sup> In application 06/201,359, Sugano claimed a priority date of 19 March 1980 based on the '931 JP application. 35 USC §119(a). (Inventor declaration in Exh. 2009). Sugano was not accorded benefit of the '931 JP application in the Declaration of Interference

1       29. According to the parties, in a previous interference,<sup>5</sup> Sugano prevailed on  
2       a Count that was directed to “A DNA which consists essentially of a DNA  
3       which codes for a human fibroblast interferon-beta polypeptide.”

4       (Transcript at 13:13-15 and, *e.g.*, ‘334, Paper 58 at 9).

5       30. It does not appear that the Count was construed expressly during the  
6       interference or on appeal. (Transcript at 13:8-16 and, *e.g.*, ‘334, Paper 58  
7       at 8-9).

8       31. It is our understanding that “human fibroblast interferon-beta polypeptide”  
9       is a polypeptide having the complete 187 amino acids of hFIF.<sup>6</sup> (*See also*,  
10       *e.g.*, ‘334, Paper 55 at 7-8).

11       32. For interference 105,334, Goeddel proposed substitute Count 2 is:

12       A DNA encoding a mature human fibroblast interferon having a  
13       total of 166 amino acids of the sequence:

14  
15       [listing of the 166 amino acids of mature human fibroblast  
16       interferon]

17  
18       and unaccompanied by a human fibroblast interferon presequence.

19  
20       (‘334, Paper 27 at 2).

21  
22       33. In interference 105,337, Goeddel proposed substitute Count 2 is:

23                               Claim 49 of Sugano, 08/463,757

24   or

25                               Claim 2 of Goeddel, 5,460,811.

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<sup>5</sup>       The Board’s decision was affirmed in *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

<sup>6</sup>       We note that the Board’s decision holding that Sugano was entitled to benefit of the ‘931 JP application was affirmed because, *inter alia*, the application set forth “the complete and correct nucleotide sequence of a DNA coding for  $\beta$ -IF.” *Fiers* at 1171.

1 ('337, Paper 39 at 3).

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3 34. Proposed Count 2 differs from Count 1 in that involved Sugano claim 49 is  
4 substituted for involved Sugano claim 31.

5 35. Claim 49 of Sugano 08/463,757 is as follows:

6 A composition comprising water and a nonglycosylated mature  
7 human fibroblast interferon polypeptide having a total of 166 amino  
8 acids and the following amino acid sequence

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10 [listing of the 166 amino acids of mature human fibroblast  
11 interferon]

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13 ...said composition being free of any glycosylated human fibroblast  
14 interferon.

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16 ('337, Paper 5).

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#### Written Description and Enablement

18 36. The involved Sugano claims include within their scope, DNA coding for

19 ('334), and the polypeptide having ('337), the amino acid sequence of the  
20 mature form of hFIF.

21 37. The Sugano involved specifications disclose the 166 amino acid sequence  
22 of the mature form of hFIF as a sequence embedded within the 187-amino  
23 acid sequence of the precursor form of hFIF at Table 5. ('337, Paper 44 at  
24 Goeddel Statement of Material Fact (smf) 6) (Exh. 2010 at 16-18, Exh.  
25 2001 at 11-12 and Exh. 2002 at 11-13).

26 38. Table 5 of the Sugano specifications is reproduced below:



Table 5

Met Ile Asn Lys Cys Leu Leu Gln Ile Ala Leu Leu Leu Cys Phe Ser Thr Thr Ala Leu Ser Met Ser Lys  
 GTC AAC ATG ACC AAC AAG TGT CTC CTC CAA ATT GCT CTC CTG TTG TGC TTC TCC ACT ACA GCT CTT TCC ATG ACC TAC  
 CAG TTG TAC TGG TTG TTC ACA GAG GAG GTT TAA CGA GAG GAC AAC ACG AAG AGG TGA TGT CGA GAA AGG TAC TCG ATG  
 20 40 60  
 Asn Lys Leu Gln Phe Leu Gln Arg Ser Ser Asn Phe Gln Cys Gln Lys Leu Leu Thr Gln Leu Asn Gln Arg Leu Gln  
 AAC TTG CTT GGA TTC CTA CAA AGA AGC ACC AAT TTT CAG TGT CAG AAG CTC CTG TGG CAA TTG AAT GGG AGG CTT GAA  
 TTG AAC GAA CCT AAG GAT GTT TCT TCG TCG TTA AAA GTC ACA GTC TTC GAG GAC ACC GTT AAC TTA CTT TCC GAA CTT  
 80 100 120 140  
 Lys Cys Leu Lys Asn Arg Met Asn Phe Asp Ile Phe Gln Gln Ile Lys Gln Leu Gln Gln Phe Gln Lys Gln Asn Ala  
 TAT TGC CTC AAG GAC AGG ATG AAC TTT GAC ATC CCT GAG GAG ATT AAG CAG CTG CAG CAG TTC CAG AAG GAG GAC GCC  
 ATA ACG GAG TTC CTG TCC TAC TTG AAA CTG TAG GGA CTC CTC TAA TTC GTC GAC GTC GTC AAG GTC TTC CTC CTG CCG  
 160 180 200 220  
 Ala Leu Thr Ile Lys Gln Met Leu Gln Asn Ile Phe Ala Ile Phe Arg Gln Asn Ser Ser Ser Thr Gln Lys Thr Asn Gln  
 GCA TTG ACC ATC TAT GAG ATG CTC CAG AAC ATC TTT GCT ATT TTC AGA CAA GAT TCA TCT AGC ACT GGC TGG AAT GAG  
 CGT AAC TGG TAG ATA CTC TAC GAG GTC TTG TAG AAA CGA TAA AAG TCT GTT CTA AGT AGA TCG TGA CCG ACC TTA CTC  
 240 260 280 300  
 Thr Ile Val Gln Asn Leu Leu Ala Ser Val Lys His Gln Ile Asn His Leu Lys Thr Val Leu Gln Gln Lys Leu Gln  
 ACT AIT GTT GAG AAC CTC CTG GCT AAT GTC TAT CAT CAG ATA AAC CAT CTG AAG ACA GTC CTG GAA GAA AAA CTG GAG  
 TGA TAA CAA CTC TTG GAG GAC CGA TTA CAG ATA GTA GTC TAT TTG GTA GAC TTC TGT CAG GAC CTT CTT TTT GAC CTC  
 320 340 360 380  
 Lys Gln Asp Phe Thr Asn Gln Lys Leu Met Ser Ser Leu His Leu Lys Arg Thr Thr Gln Asn Ile Leu His Lys Leu  
 AAT GAA GAT TTC ACC AGG GGA AAA CTC ATG ACC AGT CTG CAC CTG AAA AGA TAT TAT GGG AGG ATT CTG CAT TAC CTG  
 TTT CTT CTA AAG TGG TCC CCT TTT GAG TAC TCG TCA GAC GTC GAC TTT TCT ATA ATA CCC TCC TAA GAC GTA ATG GAC  
 400 420 440 460  
 Lys Ala Lys Gln Thr Ser His Cys Ala Thr Thr Ile Val Asn Val Gln Ile Leu Asn Asn Phe Thr Phe Thr Asn Arg  
 AAG GCC AAG GAG TAC AGT CAC TGT GCC TGG ACC ATA GTC AGA GTG GAA ATC CTA AGG AAC TTT TAC TTC ATT AAC AGA  
 TTC CCG TTC CTC ATG TCA GTG ACA CCG ACC TGG TAT CAG TCT CAC CTT TAG GAT TCC TTG AAA ATG AAG TAA TTG TCT  
 480 500 520 540  
 Leu Thr Gln Lys Leu Arg Asn  
 CTT ACA GGT TAC CTC CGA AAC TGA AGA TCT CCT AGC CTG TGC CTC TGG GAC TGG ACA ATT GCT TCA AGC ATT CTT CAA  
 GAA TGT CCA ATG GAG GCT TTG ACT TCT ASA GGA TCG GAC ACG GAG ACC CTG ACC TGT TAA CGA AGT TCG TAA GAA GTT  
 560 580 600 620  
 CCA GCA GAT GCT GTT TAA GTG ACT GAT GGC TAA TGT ACT GCA TAT GAA AGG ACA CTA GAA GAT TTT GAA ATT TTT ATT  
 GGT CGT CTA CGA CAA ATT CAC TGA CTA CCG ATT ACA TGA CGT ATA CTT TCC AGT GAT CTT CTA AAA CTT TAA AAA TAA  
 640 660 680 700  
 AAA TTA TGA GTT ATT TTT ATT TAT TTA AAT TTT ATT TTG GAA AAT AAA TTA TTT TTG GTG CAA AAG TCA AAA AAA  
 TTT AAT ACT CAA TAA AAA TAA ATA AAT TTA AAA TAA AAC CTT TTA TTT AAT AAA AAC CAC GTT TTC AGT TTT TTT  
 720 740 760

- 1
- 2 According to the involved specifications, Table 5 shows the base
- 3 sequence of the DNA which codes for human interferon polypeptide. (See
- 4 e.g., Exh. 2002 at 5:26-28).

1 39. According to the Sugano specifications, “the entire amino acid sequence  
2 for human fibroblast interferon (amino acids 1-166) and its putative signal  
3 peptide (amino acids -21 to -1)” is shown above the DNA sequences.  
4 (Exh. 2010 at 18, Exh. 2001, and 2002 at 15:1-4).

5 40. The first thirteen amino acids of the mature form of hFIF were reported in  
6 the art in February 1980 by Knight.<sup>7</sup>

7 41. The involved Sugano specifications state that “[i]t is important that in the  
8 sequence there exist without any error the base sequence (three base  
9 pairs) corresponding to the amino acid sequence from the amino-terminal  
10 to [the] 13<sup>th</sup> amino acid of the human fibroblast interferon reported by  
11 Knight...” and that “[t]his fact establishes that the #319-13 plasmid of the  
12 present invention has the human fibroblast interferon mRNA sequence.”  
13 (Exh. 2010 at 18, Exh. 2001 at 15:6-13 and Exh. 2002 at 15:5-11).

14 42. The Sugano specifications further state that “it is apparent from the data of  
15 the primary sequence that the plasmid encompasses the entire coding  
16 region of the protein of the above mRNA and probably the coding region  
17 of the signal peptide.” (Exh. 2010 at 18 and Exh. 2001 at 15:14-29 and  
18 Exh. 2002 at 15:12-16).

19 43. The Sugano specifications do not disclose a detailed method for  
20 expressing the mature form of hFIF in *E. coli*, that is, the 166 amino acid  
21 sequence absent the 21 amino acid signal peptide. (See, e.g., ‘337, Paper

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<sup>7</sup> Knight et al., *Science*, 207:525-526 (1980) (Exh. 1037).

1           63 at 3:12-16, acknowledging that plasmid #319-13 is not an expression  
2           plasmid and cannot produce recoverable amounts of hFIF.).

3       44. Goeddel concedes that as of 27 October 1980, one skilled in the art, given  
4           the sequence of Table 5 and the amino acid sequence of Knight, “should  
5           have been able to envision a DNA encoding *mature* hFIF having a *total* of  
6           166 amino acids and *unaccompanied* by the hFIF presequence.” (‘334,  
7           Paper 32 at 7 and ‘337, Paper 43 at 7, original emphasis).

8       45. Goeddel concedes that “[a]s of March 19, 1980, one of ordinary skill  
9           recognized that a DNA encoding the hFIF precursor would not be itself  
10          useful for expressing mature hFIF in *E. coli*” and that it was known that a  
11          DNA free “of [the] presequence would have to be inserted into an  
12          expression system.” (‘334, Paper 55 at 12-13 and ‘337, Paper 61 at 11).

13      46. Goeddel concedes that as of October 27, 1980, a method for tailoring the  
14          hFIF precursor gene to provide a DNA ending the mature form of hFIF  
15          having a total of 166 amino acids unaccompanied by the hFIF  
16          presequence and for the high-level expression of that tailored gene in a  
17          strain of *E. coli* had been developed and published (See, e.g., ‘337,  
18          Paper 66 at 18; Transcript at 5:13-6:5).

19      47. In particular, Goeddel concedes that David Goeddel disclosed the tailoring  
20          and high-level expression of a gene encoding the mature form of hFIF  
21          having a total of 166 amino acids and unaccompanied by a hFIF

1 sequence in a paper published 25 September 1980.<sup>8</sup> ('334, Paper 32 at  
2 14).

3 48. Goeddel points to other publications, published after October of 1980 but  
4 prior to July of 1994, reporting methods for expression of hFIF in *E. coli*.  
5 (Exh. 1108 (Second Declaration of Dr. Rik Derynck) at ¶127).

6 49. Each of the involved Sugano specifications states that the invention is "a  
7 DNA which codes for a polypeptide with interferon activity" that is to be  
8 expressed in *E. coli*. (See, e.g., Exh. 2001 at 1:40-53).

9 50. One skilled in the art during the relevant time frame "would have a Ph.D.  
10 degree or an equivalent degree, or be a highly skilled pre-doctoral fellow,  
11 with several years of research experience in molecular biology." (See,  
12 e.g., '337 at Paper 73, Goeddel admission to Sugano smf 38).

13 Benefit

14 51. Sugano filed Japanese patent application no. 33931/1980 on  
15 19 March 1980. ('931 JP application).

16 52. Sugano has filed a certified copy of the '931 JP application (Exh. 2012),  
17 an English translation of the '931 JP application, and an affidavit that the  
18 translation of the certified copy is accurate. (Exh. 2009 at 101-120).<sup>9</sup>

19 53. The '931 JP application is quite similar, but not identical, to the involved  
20 Sugano applications and patents.

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<sup>8</sup> Goeddel, *Nucl. Acids Res.* 8:4057 (1980) (Exh. 1012).

<sup>9</sup> Exhibit 2009, which is a copy of Sugano application 06/201,359, appears to be missing the page prior to that page numbered "102." However the original application file contains the missing page, i.e., page 100, which is the affidavit stating that the translation of the certified copy is accurate.

1 54. Table 5 of the '931 JP application and Table 5 of the involved Sugano  
2 application and patents appear to be the same except that the '931 JP  
3 application does not indicate by numbering the first amino acid in the  
4 Table 5 amino acid sequence and contains the word "Ter" after the last  
5 amino acid, i.e., "Asn".

6 55. The '931 JP application does not contain the statement that "the entire  
7 amino acid sequence for hFIF (amino acids 1-166) and its putative signal  
8 peptide (amino acids -21 to -1)" is shown in the DNA sequence at Table 5.

9 56. In March of 1980, "*E. coli* was known [by those skilled in the art] not to be  
10 able to glycosylate proteins faithfully." (Exh. 1108 at ¶ 36).

11 57. Dr. Thomas Roberts testified in the interference on behalf of Sugano.

12 58. Dr. Roberts testified that he has a Ph.D. in Biochemistry and Molecular  
13 Biology from Harvard University, that he was a post-doctoral fellow in the  
14 laboratory of Dr. Mark Ptashne at Harvard University between 1976 and  
15 December 1980, that he holds the position of Professor of Pathology at  
16 Harvard Medical School, and that he is the Chairman of the Division of  
17 Medical Sciences at Harvard University, the Faculty Dean at Harvard  
18 Medical School, and the Co-Chair of the Department of Cancer Biology at  
19 the Dana Farber Cancer Institute. (Exh. 2016, Robert Dec. at ¶¶2-4).

20 59. We find that Dr. Roberts is qualified to testify about technical issues  
21 relevant to the interferences.

1 60. Dr. Roberts points to publications in the art as early as 1978 suggesting  
2 “the use of bacteria to express eukaryotic proteins” and in particular  
3 interferon. (Exh. 2016 at ¶¶ 7-8).

4 61. Dr. Roberts points to over a dozen publications available in the art as early  
5 as 1978 showing that mammalian protein can be expressed in bacteria.  
6 (Exh. 2016 at ¶¶ 14-22).

7 62. Dr. Roberts points to an October 1979 Goeddel paper<sup>10</sup> showing direct  
8 expression (i.e., as opposed to expression of the precursor as a fusion  
9 protein) of human growth hormone in *E. coli*.

10 63. In that paper it is stated that the methods “are generally applicable to other  
11 polypeptides which are synthesized initially as inactive precursors and  
12 later processed, or for which full length cDNA transcripts are unavailable.”  
13 (Exh. 2021 at 548).

14 64. Dr. Roberts points to his own November 1979 paper<sup>11</sup> and a January 1980  
15 Emtage paper<sup>12</sup> which are said to provide additional examples (along  
16 with Goeddel) of a method of producing mammalian proteins in bacteria  
17 by directly expressing the gene. (Exh. 2016 at ¶ 25-26).

18 65. In the Roberts paper it is stated that “[o]ur experiments show that a  
19 message bearing a hybrid ribosome-binding site – i.e., sequences derived  
20 partly from the bacterium...and partly from the eukaryotic gene...– can be  
21 correctly translated into protein [and that] [t]his provides a rational

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<sup>10</sup> Goeddel et al, *Nature*, 281:544-548 (1979). (Exh. 2021)

<sup>11</sup> Roberts et al, *Proc. Natl. Acad. Sci. USA*, 76:5596-5600 (1979). (Exh. 2093).

<sup>12</sup> Emtage et al., *Nature*, 283:171-174 (1980). (Exh. 2094).

1 approach to the problem of obtaining expression of eukaryotic genes in  
2 bacteria.” (Exh. 2093 at 5600).

3 66. Dr. Roberts testified, and Goeddel admitted, that in view of the papers  
4 [discussed in the Roberts’ affidavit], one of skill in the art as of March 19,  
5 1980 would have at least known that certain eukaryotic genes can  
6 faithfully be expressed in bacteria, that certain bacterial promoters can  
7 drive expression of certain heterologous eukaryotic genes placed within  
8 certain plasmids, that certain mammalian proteins produced in bacteria  
9 can exhibit functionality, and that certain mammalian proteins can be  
10 transcribed and translated under the control of bacterial control elements,  
11 such that expression can be conducted without the need to make a  
12 bacterial-eukaryotic fusion protein, (‘337 at Paper 55 Goeddel response to  
13 Sugano smf 42; Exh. 2016 at ¶ 27).

14 67. Dr. Roberts points to a 1978 Backman paper<sup>13</sup> where it is stated that  
15 proteins can be directly expressed in *E. coli* using a method that “[i]n  
16 principle...should elicit high levels of expression in *E. coli* of any gene,  
17 whatever its source.” (Exh. 2016 at ¶ 31, Exh. 2095 at 65).

18 68. Dr. Roberts points to a February 1979 Roberts paper<sup>14</sup> which purports to  
19 describe a method that “in principle, will allow the same *lac* promoter to be  
20 placed at virtually any distance in front of a gene [such that] a native  
21 protein rather than a fusion protein” is produced. (Exh. 2016 at 32,  
22 Exh. 2096 at 760).

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<sup>13</sup> Backman et al, *Cell*, 13:65-71 (1978). (Exh. 2095).

<sup>14</sup> Roberts et al. *Proc. Natl. Acad. Sci. USA*, 76:760-764 (1979) (Exh. 2096).

1       69. The Roberts paper further teaches that “exonuclease III and S1 nuclease  
2       digestion used here should allow the placement of the promoter-  
3       containing fragment at virtually any distance upstream from most other  
4       genes...” (Exh. 2016 at ¶¶32 citing to pp. 760 and 764 of the Roberts  
5       paper).

6       70. We understand the methods discussed in the 1978 Backman and 1979  
7       Roberts papers are referred to by the parties as the “Ptashne lab  
8       methods”.

9       71. Dr. Roberts testified that:

10               [T]o make a human fibroblast interferon cDNA without any  
11       leader sequence, the cDNA can be digested with exonuclease III  
12       and S1 or other nucleases in order to generate a number of clones,  
13       one of which would have all of its presequence digested up to the  
14       mature ATG sequence. In fact, Goeddel’s U.S. Patent 4,342,832  
15       [issued on 3 August 1982<sup>15</sup>] explicitly teaches that exonuclease III  
16       and S1 can be used to remove leader sequences. After digestion,  
17       the clones are religated [sic], transformed into bacteria, and  
18       plasmid DNA can then be purified and analyzed, for example, by  
19       acrylamide gel analysis. Acrylamide gel analysis will allow the  
20       practitioner to determine which clones might have the entire  
21       presequence digested away. These clones can then be sequenced  
22       to confirm which ones only have the coding sequence for mature  
23       interferon, i.e., without coding sequence for the presequence.  
24       Alternatively, protein extracts from bacterial clones can be tested by  
25       immunoassays to identify potential clones that express the protein.  
26       Plasmids from these potential clones can be purified and  
27       sequenced to confirm which plasmids contain only the coding  
28       sequence for the mature interferon. Although this process can be  
29       labor intensive, the necessary methods....were well established in  
30       the art at least as of March 19, 1980.

31  
32       (Exh. 2016 at ¶¶ 46 and citing to ¶¶ 37-41).

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<sup>15</sup> Because this Goeddel patent issued after March 19, 1980 we do not consider it to be part of the knowledge of one skilled in the art as of the filing date of the ‘931 JP application.



1       72. On cross-examination, Dr. Roberts testified that screening by size was a  
2       method available at the time of the publication of the Roberts February  
3       1979 paper. (Exh. 2181 at 34:11-35:4).

4       73. On cross-examination, Dr. Roberts testified that exonuclease III and S1  
5       would be used to make a clone that would have a “certainty” of achieving  
6       synthesis of the mature protein. (Exh. 2181 at 68:9-70:20).

7       74. On cross-examination, Dr. Roberts testified that using only the Ptashne  
8       lab methods available in 1980 (and not the beta galactosidase screening  
9       method of Guarente<sup>16</sup>), it would take a “[c]ouple of months” to be  
10      successful in expressing mature hFIF. (Exh. 2181 at 71:23-73:21).

11      75. Dr. Roberts pointed to papers published prior to March of 1980 reporting  
12      that non-glycosylated interferons expressed in bacteria would be expected  
13      to be active. (Exh. 2016 at ¶¶ 99-101).

14      76. Dr. Roberts testified that one skilled in the art, having reviewed the  
15      published art as of March of 1980, would have found it likely that  
16      completely non-glycosylated human interferons would maintain activity.  
17      (Exh. 2016 at ¶¶ 99-100).

18      77. Drs. Jean Content and Gail Lauer have also presented testimony in the  
19      interferences on behalf of Sugano.

20      78. Based on their testimony regarding their educational and professional  
21      backgrounds and education, we find Drs. Content and Lauer to be

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<sup>16</sup> Guarente et al, *Cell*, 20:543-553(1980) (Exh. 2132).

1 qualified to testify regarding technical issues relevant to the interferences.  
2 (Exh. 2145 at ¶¶ 2-5; Exh. 2146 at ¶¶ 2 and 3).

3 79. Drs. Content and Lauer testified that one skilled in the art could have used  
4 the Ptashne lab methods to make the DNA encoding mature hFIF as of  
5 19 March 1980 ( Exh. 2145 at ¶¶ 10 and 13; Exh. 2146 at ¶¶ 6 and 9).

6 80. Dr. Rik Dernyck testified in the interference on behalf of Goeddel.  
7 (Exh. 1108).

8 81. Dr. Dernyck testified that he has a Ph.D. in Molecular Biology from the  
9 University of Ghent, Belgium and was a predoctoral fellow/research  
10 associate with Dr. Walter Fiers. (Exh. 1108 at ¶ 2).

11 82. Dr. Dernyck testified that he is a Professor in the Department of Growth  
12 and Development and the Department of Cell and Tissue Biology at the  
13 University of California at San Francisco, that he is the co-director of the  
14 UCSF Institute for Regeneration Medicine and Director of its Program in  
15 Craniofacial and Mesenchymal Biology, and that he has conducted  
16 research in molecular biology and recombinant DNA technology and  
17 worked in the molecular biology departments at Genentech, Inc., the real  
18 party in interest for Goeddel. (Exh. 1108 at ¶¶ 3-5)

19 83. We find Dr. Dernyck to be qualified to testify regarding technical issues  
20 relevant to the interferences.

21 84. Dr. Dernyck testified that one skilled in the art, given the sequence of  
22 Table 5 and the amino acid sequence of Knight, both disclosed in the  
23 '931 JP application, should have been able to envision a DNA encoding

1 mature hFIF having a total of 166 amino acids and unaccompanied by the  
2 hFIF presequence. (Exh. 1108 at ¶ 59).

3 85. Dr. Dernyck acknowledged published reports in the art showing  
4 expression of mammalian proteins in *E. coli*, however, Dr. Dernyck  
5 testified that:

6 The observation, e.g., that a particular protein is stable in *E.*  
7 *coli* or that a particular protein can be expressed in *E. coli* was not  
8 predictive of successful expression of another selected protein.  
9 The reports discussed....above therefore would have been  
10 considered by those of ordinary skill to be more of a collection of  
11 anecdotal reports than a coherent body of art.

12  
13 (Exh. 1108 at ¶ 53).

14 86. Dr. Dernyck acknowledged that the “Ptashne [lab] methods” would yield  
15 the “desired clones” but with such low frequency that, given screening  
16 techniques available as of October of 1980, the “identification of rare  
17 isolates expressing mature human fibroblast interferon.....within an  
18 immense population of clones would have been unduly burdensome or  
19 impossible....” (Exh. 1108 at ¶ 83).

20 87. Dr. Dernyck testified further that “[t]his conclusion is supported by the  
21 actual frequency ultimately reported, in October 1980 from the Ptashne  
22 lab, i.e., desired clones were found at a frequency of 0.01%.” (Exh. 1108  
23 at ¶ 83).

24 88. Dr Dernyck points to “a later publication from the same [Ptashne]  
25 laboratory”, i.e., the Guarente paper, that is said to have provided for  
26 better screening methods, i.e., the  $\beta$ -galactosidase screening method.  
27 (Exh. 1108 at ¶ 61).

1       89.       Sugano points to a statement said to have been given by Dr.  
2       Dernyck in an EPO opposition proceeding in 1996 indicating that Dr.  
3       Dernyck  
4       pursued this goal [of expressing hFIF in E. coli] with the methodology  
5       available to us at that time, and no new technology was required to  
6       achieve the expression of IFN-  $\beta$ , which we accomplished about two  
7       months after obtaining possession of the full length cDNA encoding it [in  
8       late February of 1980].  
9  
10       ('337, Paper 77 at 5 and Exh. 2144 at ¶¶ 4-5).  
11       90. On cross-examination, Dr. Dernyck confirmed that he made the statement  
12       and that his understanding was:  
13       IFN-B is a polypeptide having interferon activity, and  
14       he had methodology available to him in the lab that others did not have.  
15       (Exh. 2162 at 55:9-61:6).  
16       91. Dr. Paula Pitha-Rowe testified in the interference on behalf on Goeddel.  
17       (Exh. 1080).  
18       92. Dr. Pitha-Rowe testified that she has a Ph.D. in Biochemistry from the  
19       Academy of Science in Prague, Czechoslovakia and that she has been  
20       working and publishing in the field of interferons since 1971. (Exh. 1080  
21       at ¶¶ 2-3).  
22       93. Dr. Pitha-Rowe testified that she is a professor of oncology with a joint  
23       appointment in molecular biology at Johns Hopkins University School of  
24       Medicine. (Exh. 1080 at ¶ 4).  
25       94. We find that Dr. Pitha-Rowe is qualified to testify about issues relevant to  
26       this interference.

1 95. Dr. Pitha-Rowe testified that, despite papers published prior to March of  
2 1980 reporting that non-glycosylated interferons expressed in bacteria  
3 would be expected to be active, “researchers as of March 19, 1980 would  
4 not have been able to determine which of the published data were clear  
5 enough to show convincingly whether or not glycosylation is required for  
6 biological activity of human fibroblast interferon.” (Exh. 1080 at ¶ 49).

7 96. Dr. Pitha-Rowe is listed as an author in papers<sup>17</sup> published prior to March  
8 of 1980 indicating that non-glycosylated hFIF might be biologically active.  
9 (Exh. 2175 and Exh. 2106).

10 97. A review article by Stewart<sup>18</sup> published in 1979 stated that “[t]hese data  
11 suggest that carbohydrate-free interferons are equally as active as native  
12 glycosylated interferons.” (Exh. 1102 at 181).

13 98. In *Goeddel v. Weissman*,<sup>19</sup> the Board determined that an “an April ’80 EPO  
14 application [did] not constitute a constructive reduction to practice of; the  
15 count” because of a lack of enablement for microbially producing mature  
16 human leuckocyte interferon. (Exh. 1137 at 13).

17 99. It does not appear that all the publications before us, including those  
18 publications describing the Ptashne lab methods, were considered by the  
19 Board in coming to the determination of a lack of enablement.

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<sup>17</sup> Raj et al., *Proc. Natl. Acad. Sci. USA*, 74(4):1483-1487 (1977) (Exh. 2175) and Reynolds et al., *Proc. Natl. Acad. Sci. USA*, 72(12):4881-4885 (1975) (Exh. 2106).

<sup>18</sup> Stewart, *The Interferon System*: 134-183 (1979) (Exh. 1102).

<sup>19</sup> *Goeddel v. Weissmann*, Interference No. 101,601 (BPAI 1995) (final decision) (Ex. 1137), corrected by *Goeddel v. Weissmann*, Interference No. 101,601 (BPAI 1996) (correction on reconsideration) (Ex. 1138).

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1 [166 amino acids of the mature form of hFIF].

2  
3 (FF 8 and 10).

4  
5 We construe claim 6 as requiring DNA that codes for the 166 amino acids  
6 of the mature form of hFIF and as including DNA that codes for the 166 amino  
7 acids plus others. We note, in the context of claim 6, the use of “consisting  
8 essentially of” allows for additional DNA that does not “materially affect [its] basic  
9 and novel characteristic(s)” *In re Herz*, 537 F.2d 549, 551-552 (CCPA 1976).  
10 Goeddel argues that the open language of claim 6 encompasses the precursor  
11 form of hFIF. (‘334, Paper 27 at 9-10). Sugano has not explained why additional  
12 DNA, such as the additional DNA that would allow for DNA coding for the amino  
13 acid sequence of the mature form of hFIF is excluded. In particular, Sugano, in  
14 its opposition, does not provide a satisfactory explanation or evidence  
15 establishing that additional DNA would materially affect the basic and novel  
16 characteristics of the invention.

17 Sugano agrees that if we determine that Count 1 is improper, then Count  
18 2 is an appropriate Count.

19 Proposed Count 2 is as follows:

20 A DNA encoding a mature human fibroblast interferon having a  
21 total of 166 amino acids of the sequence:

22  
23 [listing of the 166 amino acids of mature human fibroblast  
24 interferon]

25  
26 and unaccompanied by a human fibroblast interferon presequence.

27  
28 (FF 32).

29

1           We construe Count 2 as limited to that DNA that encodes for only the 166  
2   amino acids of the mature form of hFIF and not including that DNA that also  
3   would encode for the additional 21 amino acids of the hFIF presequence. We  
4   note that Count 2 is not open to hFIF “having a total of” more than 166 amino  
5   acids given the context of the claim. In particular, since Count 2 indicates “a  
6   total” of the 166 amino acids listed, DNA encoding additional amino acids is  
7   excluded.

8           We GRANT Goeddel Motion 1 in interference 105,334.

9           Goeddel provides persuasive reasons why, and Sugano does not  
10   disagree that, the same claims that were designated as corresponding to Count 1  
11   should be designated as corresponding to Count 2. The interference will be  
12   redeclared to substitute Count 2 for Count 1 and the same claims that were, in  
13   the Declaration (Paper 1), designated as corresponding to Count 1 will also be  
14   designated as corresponding to Count 2.

15          Goeddel noted that Sugano did not move, contingent on the grant of  
16   Goeddel motion 1, for benefit of the ‘931 JP application. Nonetheless, we will  
17   consider the Sugano motion for benefit as to Count 1 as a motion for benefit as  
18   to Count 2 since, in that motion, Sugano addressed the issue of whether the ‘931  
19   JP application is a constructive reduction to practice for what we have  
20   determined to be the scope of Count 2. Moreover, Goeddel opposed the Sugano  
21   motion for benefit as though Count 1 was limited to a DNA encoding mature hFIF  
22   having a total of 166 amino acids and unaccompanied by its presequence.  
23   (‘334, Paper 55 at 9).



2 The parties agree that the subject matter of the interference should be  
3 limited to mature hFIF. (FF 28). Sugano agrees that, “if [the Board] find[s] that  
4 the claims [of Count 1] read on the precursor, the Count proposed by Goeddel  
5 would be appropriate...”. (Transcript at 32:1-2).

6 Count 1 in interference 105,334 includes claim 31 the ‘757 Sugano  
7 application. (FF 22).

8 Claim 31 of the ‘757 application is as follows:

9 Recombinant human fibroblast  $\beta$ 1 interferon having the amino acid  
10 sequence:

11  
12 [listing of the 166 amino acids of mature human fibroblast  
13 interferon].

14  
15 (FF 23).

16 We construe claim 31 as requiring the 166 amino acids of the mature form  
17 of hFIF and as including the 166 amino acids plus others. Goeddel argues that  
18 the open language of claim 31 encompasses for the precursor form of hFIF.  
19 (‘337, Paper 39 at 7-8). We do not construe the term “having” as precluding the  
20 presence of additional amino acids. See *Regents of the Univ. of Cal. v. Eli Lilly &*  
21 *Co.*, 119 F.3d 1559, 1573 (Fed. Cir. 1997) (In the claim, “[a] DNA transfer vector  
22 comprising an inserted cDNA having a [DNA] sequence coding for human  
23 [PI]....”, the “word ‘having’ still permitted inclusion of other moieties’.). Moreover,  
24 it is not apparent to us, nor has Sugano pointed out in its opposition, why the  
25 underlying specification would necessitate a closed construction. See *Lampi*  
26 *Corp. v. American Power Products, Inc.* 228 F.3d 1365, 1376 (Fed. Cir. 2000).

1 In interference 105,337, Goeddel proposed substitute Count 2 is:

2 Claim 49 of Sugano, 08/463,757

3 or

4 Claim 2 of Goeddel, 5,460,811.

5 (FF 33).

6 Proposed Count 2 differs from Count 1 in that involved Sugano claim 49 is  
7 substituted for involved Sugano claim 31. Claim 49 of Sugano 08/463,757 is as  
8 follows:

9 A composition comprising water and a nonglycosylated  
10 mature human fibroblast interferon polypeptide having a total of 166  
11 amino acids and the following amino acid sequence

12  
13 [listing of the 166 amino acids of mature human fibroblast  
14 interferon]

15  
16 ...said composition being free of any glycosylated human fibroblast  
17 interferon.

18  
19 (FF 35).

20 Goeddel claim 2 is similarly limited to claim a composition comprising  
21 water and a nonglycosylated polypeptide having a “total” of the 166 amino acids  
22 of the mature form of hFIF. (FF 24).

23 Thus, we construe the “nonglycosylated polypeptide” of proposed Count 2  
24 as limited to the 166 amino acids of the mature form of hFIF. We note that  
25 Count 2 is not open to hFIF “having” more than 166 amino acids given the  
26 context of the claim. In particular, since Count 2 indicates “a total” of the 166  
27 amino acids listed, DNA encoding additional amino acids is excluded.

28 We GRANT Goeddel Motion 1 in interference 105,337.

1           Goeddel provides persuasive reasons why the same claims, but for  
2   Sugano claim 50, that were designated as corresponding to Count 1 should be  
3   designated as corresponding to Count 2. Sugano does not oppose the claim  
4   designations proposed by Goeddel. In its opposition, Sugano states that it  
5   “recognizes that claim 50, as presently pending, is incorrect and requires  
6   amendment [since] [t]he deposited plasmid is not an expression plasmid and  
7   therefore cannot produce recoverable amounts of recombinant human fibroblast  
8   interferon.” (‘337, Paper 63 at 3; FF 43). We take this as an admission by  
9   Sugano that claim 50 is not patentable. A judgment that Sugano claim 50 is  
10   unpatentable will be entered in a separate paper.

11           The interference will be redeclared to substitute Count 2 for Count 1 and  
12   the same claims that were designated as corresponding to Count 1, but for  
13   Sugano claim 50, will also be designated as corresponding to Count 2.

14           Goeddel notes that Sugano did not move, contingent on the grant of  
15   Goeddel motion 1, for benefit of the ‘931 JP application. We will consider the  
16   Sugano motion for benefit as to Count 1 as a motion for benefit as to Count 2  
17   since, in that motion, Sugano addresses the issue of whether the ‘931 JP  
18   application is a constructive reduction to practice for what we have determined to  
19   be the scope of Count 2. Moreover, Goeddel opposed the Sugano motion for  
20   benefit as though Count 1 was limited to mature hFIF having a total of 166 amino  
21   acids and unaccompanied by its presequence. (‘337, Paper 61 at 8-9).

1           B.       Written Description and Enablement

2           Goeddel moves for judgment that the involved claims in each interference  
3           are unpatentable for lack of written description and lack of enablement.

4           To satisfy the written description requirement, a patent specification must  
5           describe the claimed invention in sufficient detail that one skilled in the art can  
6           reasonably conclude that the inventor had possession of the claimed invention.  
7           *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). “Although  
8           [the applicant] does not have to describe exactly the subject matter claimed ...  
9           the description must clearly allow persons of ordinary skill in the art to recognize  
10          that [the applicant] invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012,  
11          (Fed.Cir.1989) (citations omitted). When determining whether an inventor has  
12          provided adequate written description, either explicitly or inherently, we consider  
13          the disclosure as a whole. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.  
14          Cir. 2000).

15          The enablement requirement of 35 U.S.C. § 112, ¶1, is separate and  
16          distinct from the written description requirement. *Vas-Cath*, 935 F.2d at 1567.  
17          The state of the art existing at the filing date of the application is used to  
18          determine whether a particular disclosure is enabling as of the filing date. *Chiron*  
19          *Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). The sufficiency  
20          of an application’s disclosure under 35 USC §112, ¶1 must be judged as of the  
21          filing date of the application and not the filing date of any ancestor applications.  
22          *Reiffin* at 1346.

1            “It is the specification, not the knowledge of one skilled in the art, that must  
2     supply the novel aspect of an invention in order to constitute adequate  
3     enablement.” *Genentech Inv. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.  
4     Cir. 1997). However, the specification need not disclose what is well-known to  
5     those skilled in the art and preferably omits that which is well-known to those  
6     skilled and already available to the public. *Hybritech, Inc. v. Monoclonal*  
7     *Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

8            We consider whether an undue amount of experimentation would have  
9     been required to practice the claimed invention in determining whether an  
10    enabling disclosure has been provided. The test for whether undue  
11    experimentation would have been required

12           is not merely quantative since a considerable amount of experimentation  
13           is permissible, if it is merely routine, or if the specification in question  
14           provides a reasonable amount of guidance with respect to the direction in  
15           which the experimentation should proceed to enable the determination of  
16           how to practice a desired embodiment of the invention claimed.

17  
18     *Ex parte Jackson*, 217 USPQ 804, 807 (BPAI 1982), cited with approval in *PPG*  
19     *Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

20           The moving party bears the burden of proof to establish that it is entitled to  
21    the requested relief. Bd. R. 121(b). Thus, Goeddel has the burden of showing  
22    that the Sugano claims lack written description or enablement.

23           Goeddel correctly notes that amino acid sequence and encoding DNA of  
24    hFIF is not explicitly disclosed in the Sugano specifications.. (e.g., ‘337,  
25    Paper 44 at 9). However, Goeddel concedes that one skilled in the art, given the  
26    sequence of Table 5 and the amino acid sequence of Knight, “should have been

1 able to envision a DNA encoding mature hFIF having a total of 166 amino acids  
2 and unaccompanied by the hFIF presequence.” (FF 44). We agree given that:

3 (1) Table 5 discloses the entire precursor sequence which includes  
4 within it the mature sequence (FFs 37- 38),

5 (2) Knight is discussed in the Sugano specifications as disclosing the  
6 first 13 amino acids of mature hFIF (FF 40), and

7 (3) Table 5 shows the end point of mature hFIF (FF 38)  
8 the amino acid, and DNA sequence encoding, of mature hFIF would be  
9 readily apparent.

10 Nonetheless, Goeddel argues that Sugano did not provide any description  
11 of a method for expressing the hFIF gene in a microorganism. According to  
12 Goeddel, “[i]n view of the unpredictable nature of the then-nascent field of  
13 genetic engineering and heterologous expression of proteins”, Sugano must  
14 have described a method for expressing the hFIF DNA in order to have  
15 possession of the claimed subject matter (‘337, Paper 44 at 16-18). Sugano  
16 concedes that the plasmids it discloses would not function to express mature  
17 hFIF (FF 43). Sugano nonetheless asserts that one skilled in the art would have  
18 been able to practice the claimed invention without resorting to undue  
19 experimentation given the state of the prior art.

20 At the outset we note that Sugano’s involved ‘567 patent was filed 6  
21 March 1995 and Sugano’s involved ‘859 patent was filed 27 October 1980. (FF  
22 2). Sugano’s involved ‘757 application was filed 5 June 1995. (FF 16). Thus the  
23 relevant date for assessing whether the Sugano claims lack an enabling

1 disclosure as to the '567 patent and the '757 application is no earlier than 6  
2 March 1995. See *Chiron* at 1254. *Reiffin* at 246. We have not been directed to  
3 evidence showing that the field of the heterologous expression of proteins was  
4 "nascent" or "unpredictable" in March of 1995. There appears to be no dispute  
5 that at least one method for expressing, in *E. coli*, the mature human fibroblast  
6 interferon having a total of 166 amino acids and unaccompanied by its  
7 presequence was known and published in the art as of  
8 27 October 1980. (FF 46). Moreover as Goeddel acknowledges, methods of  
9 expressing mature hFIF in *E. coli* have been published after October of 1980 but  
10 prior to July of 1994. (FF 48).

11 Thus, we do not fully understand Goeddel's argument that one skilled in  
12 the art would have been unable to practice the claimed invention given the  
13 Sugano specifications. First of all, the relevant date for evaluating each of the  
14 Sugano specifications is its filing date, the earliest of which is in October of 1980.  
15 The record establishes that at least one method of expressing hFIF had been  
16 known in the art for over fourteen years by the time the '757 application and the  
17 application underlying the '567 patent were filed. (FF 46). Secondly, when we  
18 look to Sugano's earliest accorded benefit date of 27 October 1980 (and the filing  
19 date of the application underlying the '859 patent), we note that the parties agree  
20 that a method for expressing hFIF was known and had published at that time.  
21 (FFs 46-47).<sup>21</sup>

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<sup>21</sup> Goeddel states that its enablement motions address "enablement as of October 27, 1980 since that is the earliest date accorded Sugano in the

1           Goeddel argues that “the art cannot be a *substitute* for a *basic enabling*  
2   *disclosure*, i.e., a specification that is *devoid* of any disclosure of a method of  
3   making the claimed subject matter cannot rely on the art for enablement of its  
4   claims.” (‘337, Paper 43 at 15, original emphasis). In other words, even though  
5   Goeddel concedes that a method for expressing mature hFIF in *E. coli* was  
6   known in the art at the time of filing, we understand it to be Goeddel’s position  
7   that the Sugano specifications did not provide sufficient direction to these  
8   methods . However, given that at least one method for expressing mature hFIF  
9   was known and published in the art at the time each of the Sugano applications  
10   was filed (FFs 46-48), we are not convinced that a detailed description of a  
11   method of expression was necessary to show possession of the claimed  
12   invention. Nor are we convinced that practicing the claimed invention would  
13   have required undue experimentation. In the circumstances before us, Sugano  
14   need not have included a detailed method for expression to provide enablement  
15   since that methods were already available to the public. See *Hybritech* at 1384.

16           Goeddel directs us to *Genentech*, 108 F.3d at 1366 and *Automotive*  
17   *Technologies v. BMW*, 501 F.3d 1274 (Fed. Cir. 2007) in support of its position  
18   that, given the state of the art, Sugano must have expressly described a method  
19   of expression in order to have provided enablement.

20           We do not find *Genentech* and *Automotive Technologies* to support  
21   Goeddel’s position given the record before us. In *Genentech* the specification  
22   described an invention that avoided the difficulties of cleavage by providing

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Declaration.” (See, e.g., ‘334, Paper 32 at 7, fn. 2) However, Goeddel did not file  
a motion attacking the benefit date accorded to Goeddel in either interference.



1 human growth hormone (hgh) unaccompanied by any other extraneous proteins.  
2 When Genentech claimed a method requiring the steps of expressing a DNA  
3 encoding for hgh conjugate protein and then cleaving the conjugate protein by  
4 enzymatic action, the Court determined that Genentech was “attempting to  
5 bootstrap a vague statement of a problem into an enabling disclosure sufficient to  
6 dominate someone else’s solution of the problem.” In Genentech the method  
7 comprising the cleavage step was the novel aspect of the claimed invention yet  
8 the Court found that “[the] specification is so lacking with respect to the limitation  
9 [to enzymatic cleavage] that providing testimony regarding the skill in the art has  
10 been an exercise in futility.” The Court further determined that practicing the  
11 invention would require undue experimentation. *Genentech*, 108 F.3d at 1367).

12 In *Automotive Technologies*, the claims required a “responsive means”  
13 which included an “electronic sensor” but the inventor, “admitted that the  
14 specification fails to disclose structure for any of the technologies mentioned [for  
15 electronic sensing].” *Id.* at 1283. Moreover, expert testimony and the inventor’s  
16 own testimony indicated that functional electronic sensors were not known in the  
17 art at the relevant time.

18 Unlike in *Genentech* and *Automotive Technologies*, the Sugano  
19 specifications provide sufficient detail of what the claimed invention is, i.e.,  
20 mature hFIF polypeptides or DNA encoding the polypeptide by providing the  
21 nucleotide and amino acid structures and direction that the polypeptide could be  
22 expressed in *E. coli*. While the involved Sugano specifications themselves did  
23 not disclose details of a method of expressing the hFIF in *E. coli* (including a step

1 of provided the DNA molecule encoding mature hFIF), at least one method of  
2 expressing hFIF in *E. coli* was well known in the art and published by the time the  
3 involved applications were filed. (FF 47). Furthermore, we do not determine that  
4 the involved technology was “unpredictable” or in its “early stages of  
5 development” at the time the involved applications were filed such that undue  
6 experimentation would have been required to make the claimed invention.  
7 While we agree that a specification may not describe a claimed invention if it  
8 merely provides a “germ of an idea” of the claimed subject matter, the Sugano  
9 specifications do not fall into that category. *Cf. Genentech*, 108 F.3d at 1366-  
10 1368.

11       Goeddel argues that the September 1980 Goeddel publication was the  
12 result of the work of one “extraordinarily skilled in the art.” (e.g., ‘337, Paper 43 at  
13 15). We are not persuaded by this argument since: (1) the publication itself  
14 reported a method for expressing mature hFIF in *E. coli* and thus, after  
15 publication, became part of the knowledge of one of ordinary skill in the art and  
16 (2) at the time the ‘757 application and the application underlying the ‘567 patent  
17 were filed, additional publications reported a method for expression of hFIF in  
18 *E. coli*. (FF 48).

19       In interference 105,334, Goeddel motions 6 and 7 are DENIED.

20       In interference 105,337, Goeddel motions 5 and 6 are DENIED.

21       C. Benefit

22       Sugano moves for benefit of its ‘931 JP application as to Count 1. We  
23 grant Goeddel’s motion to substitute Count 2 in each of interferences 105,334

1 and 105,337. Sugano did not move, contingent on the grant of the Goeddel  
2 motion to substitute a count, for benefit of the JP application as to Count 2.  
3 Nonetheless, we consider Sugano's benefit motion as a motion for benefit as to  
4 Count 2 since the motion (as well as Goeddel's opposition) address whether the  
5 JP application provided a constructive reduction to practice within the scope of  
6 Count 2.

7 In order to be entitled to benefit for the purpose of priority for an earlier  
8 filed application that application must contain a described and enabled  
9 anticipation under 35 U.S.C. §102(g)(1) that has been continuously disclosed  
10 through a chain of patent applications including the involved application or  
11 patent. For the chain to be continuous, each subsequent application must have  
12 been copending under 35 U.S.C. §120 or §121 or timely filed under 35 U.S.C.  
13 §119 or §365(a). Bd. R. 201.

14 In addition, a party seeking priority benefit of an earlier filed application  
15 must provide a copy of the application along with a certified translation of a non-  
16 English application. Standing Order at ¶ 208.4.1, Bd. R. 154(b).

17 As the moving party, Sugano has the burden of establishing that it is  
18 entitled to the requested relief. Bd. R. 121(b).

19 Sugano seeks priority benefit of the '931 JP application filed 19 March  
20 1980. It is not disputed that the chain of applications leading back to the JP  
21 application were timely filed. Sugano has supplied a copy of the JP application  
22 as well as a certified translation of the application. (FF 52).

1           The issue before us is whether the '931 JP application provided written  
2   description and enablement for DNA coding for ('334), or the polypeptide having  
3   ('337), a total of the 166 amino acids of the mature form of hFIF.

4           The '931 JP disclosure is quite similar, but is not identical, to the  
5   disclosure in the involved Sugano specifications. (FF 53). However, the '931 JP  
6   application does not indicate by numbering the first amino acid in the Table 5  
7   amino acid sequence and contains the word "Ter" after the last amino acid, i.e.,  
8   "Asn" but otherwise Table 5 of the '931 JP application and Table 5 of the involved  
9   Sugano applications and patents appear to be the same. (FF 54)

10          The '931 JP application does not contain the statement that "the entire  
11   amino acid sequence for hFIF (amino acids 1-166) and its putative signal peptide  
12   (amino acids -21 to -1)" is shown in the DNA sequence at Table 5. (FF 55).

13          Nonetheless, for much the same reasons we noted above in denying the  
14   Goeddel motion for lack of written description support, we find that the '931  
15   application provided sufficient written description and enablement for the DNA  
16   coding for, and the polypeptide having the amino acid sequence of, mature hFIF.  
17   The sequences of mature hFIF DNA or polypeptide are not explicitly disclosed.  
18   As Goeddel concedes, one skilled in the art, given the sequence of Table 5 and  
19   the amino acid sequence of Knight, "should have been able to envision a DNA  
20   encoding mature hFIF having a total of 166 amino acids and unaccompanied by  
21   the hFIF presequence." (FF 44). We agree given that:

22          (1)     Table 5 disclosed the precursor sequence (FFs 53-55),

1           (2) Knight is discussed in the '931 JP application as disclosing the first  
2 13 amino acids of mature hFIF (FFs 41 and 53-55), and

3           (3) Table 5 discloses the end point of hFIF (FFs 53-55)  
4 the amino acid of, and DNA sequence encoding, mature hFIF would be  
5 readily apparent.

6           The '931 JP application itself does not disclose in detail how to express  
7 mature hFIF in *E. coli*, which would include the step of making the DNA molecule  
8 needed to express mature hFIF. Thus, we find that the guidance provided by the  
9 '931 JP application is minimal. However, in evaluating whether sufficient  
10 enablement was provided we look not just to the '931 JP application itself but  
11 also to, *inter alia*, the level of skill in the art and the state of the art at the time of  
12 filing, i.e., 19 March 1980. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)  
13 ("Factors to be considered in determining whether a disclosure would require  
14 undue experimentation ...include ... (2) the amount of direction or guidance  
15 presented... (5) the state of the prior art, (6) the relative skill of those in the  
16 art....).

17           We determine that Sugano has established that methods were known at  
18 the relevant time for directly expressing proteins in *E. coli* and that one skilled in  
19 the art would have been able to express mature hFIF using techniques that were  
20 known in the art. Sugano has also established that one skilled in the art would  
21 have expected that these non-glycosylated proteins would obtain at least some  
22 biological activity. Based on the testimony of Dr. Roberts and the testimony of  
23 Drs. Content and Lauer, and the publications pointed out to us, Sugano has set

1    forth a *prima facie* case showing that it is entitled to benefit of the '931 JP  
2    application.

3            In particular we credit Dr. Robert's testimony that:

4            [T]o make a human fibroblast interferon dDNA without any leader  
5            sequence, the cDNA can be digested with exonuclease III and S1  
6            or other nucleases in order to generate a number of clones, one of  
7            which would have all of its presequence digested up to the mature  
8            ATG sequence. In fact, Goeddel's U.S. Patent 4,342,832 [issued  
9            on 3 August 1982<sup>22</sup>] explicitly teaches that exonuclease III and S1  
10           can be used to remove leader sequences. After digestion, the  
11           clones are religated [sic], transformed into bacteria, and plasmid  
12           DNA can then be purified and analyzed, for example, by acrylamide  
13           gel analysis. Acrylamide gel analysis will allow the practitioner to  
14           determine which clones might have the entire presequence  
15           digested away. These clones can then be sequenced to confirm  
16           which ones only have the coding sequence for mature interferon,  
17           i.e., without coding sequence for the presequence. Alternatively,  
18           protein extracts from bacterial clones can be tested by  
19           immunoassays to identify potential clones that express the protein.  
20           Plasmids from these potential clones can be purified and  
21           sequenced to confirm which plasmids contain only the coding  
22           sequence for the mature interferon. Although this process can be  
23           labor intensive, the necessary methods....were well established in  
24           the art at least as of March 19, 1980.

25  
26            (FF 71).

27            To the extent that Dr. Robert's testimony conflicts with the testimony of Dr.  
28    Dernyck on whether one skilled in the art could have made mature hFIF in view  
29    of the guidance provided in the '931 JP application and techniques known in the  
30    art, in particular the Ptashne lab methods, we credit Dr. Robert's testimony as  
31    well as the testimony of Drs. Content and Lauer (FF 79) over that of Dr. Dernyck.

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<sup>22</sup>        Because the Goeddel patent issued after 19 March 1980, we do not consider it as part of the knowledge of one skilled in the art at the time of the filing of the '931 JP application.

1 First, we note that Dr. Dernyck agrees that, given the sequence of  
2 precursor hFIF and the disclosure of Knight (both found in the '931 JP  
3 application), one skilled in the art should have been able to envision the  
4 sequence of mature hFIF. (FF 84).

5 Secondly, we note the Dr. Dernyck agrees that the Ptashne lab methods  
6 would have allowed for production of clones that would express mature hFIF.  
7 (FF 86). While Dr. Dernyck testified that there would be a large amount of  
8 screening necessary to identify the appropriate clones and that the necessary  
9 screening would have been "unduly burdensome," (FF 86) we are not convinced  
10 that the screening required would amount to undue experimentation. See *Wands*,  
11 858 F.2d at 737, (citing *In re Jackson*, 217 USPQ 804, 807 (BPAI 1982). "The  
12 test is not merely quantitative, since a considerable amount of experimentation is  
13 permissible, if it is merely routine, or if the specification in question provides a  
14 reasonable amount of guidance with respect to the direction in which the  
15 experimentation should proceed."). Even if the desired clones were only found at  
16 a frequency of .01% (FF 87), it does not follow that the amount of  
17 experimentation needed to screen for the clones was undue. Dr. Rogers testified  
18 that there were multiple known methods of screening that would result in  
19 identification of clones useful for the expression of mature hFIF with only routine  
20 experimentation. (FFs 71 -74). Moreover, while, as noted by Goeddel, it  
21 appears that a better method for screening was developed after  
22 19 March 1980, it does not follow that the former procedure would not have  
23 worked sufficiently. (FF 88). We are not convinced, based on the record before

1 us, that the screening procedures required undue experimentation. To the extent  
2 that Drs. Derynck and Roberts have provided conflicting testimony on the amount  
3 of experimentation that would have been required, we credit Dr. Roberts'  
4 testimony.

5 We also note that Dr. Derynck had provided a sworn statement in another  
6 proceeding indicating that only methods known in the art as of March of 1980  
7 were used to express hFIF. (FF 89). Dr. Derynck, on cross-examination in the  
8 interferences, disputes that he was speaking only of mature hFIF or methods  
9 available to the public in the sworn statement. (FF 89). The lack of a clear and  
10 consistent position by Dr. Derynck is an additional reason that we do not credit  
11 Dr. Derynck's testimony over Dr. Roberts' testimony.

12 We also have considered Goeddel's argument that in *Goeddel v.*  
13 *Weissman*, the Board determined that a 1980 EPO application did not amount to  
14 a constructive reduction to practice because of a lack of enablement for  
15 microbially produced mature human leukocyte interferon. (FF 98). We are not  
16 persuaded that we should adopt the Board's position in *Weissmann*. For  
17 example, the record before us is different than in *Weissmann*. We note that it  
18 does not appear that the Ptashne lab methods were considered by the Board in  
19 *Weissmann*. (FF 99).

20 Dr. Roberts pointed to papers published prior to March of 1980 reporting  
21 that non-glycosylated interferons expressed in bacteria would be expected to be  
22 active. (FF 75). Dr. Roberts testified that one skilled in the art, having reviewed



1 the published art as of March of 1980, would have found it likely that completely  
2 non-glycosylated human interferons would maintain activity. (FF 76).<sup>23</sup>

3 Dr. Robert's testimony is consistent with the Stewart review article  
4 published in 1979 where it is noted that previously published data suggests that  
5 "carbohydrate-free interferons are equally as active as native glycosylated  
6 interferons." (FF 97).

7 Dr. Pitha-Rowe testified that, despite reports in the art that non-  
8 glycosylated interferons would be expected to be active, "researchers as of March  
9 19, 1980 would not have been able to determine which of the published data were  
10 clear enough to show convincingly whether or not glycosylation is required for  
11 biological activity of human fibroblast interferon." (FF 95).

12 We have considered Dr. Pitha-Rowe's criticisms of the particular papers  
13 reporting activity for non-glycosylated interferons. However, when we consider  
14 the papers published as of March 1980 (including those by Dr. Pitha-Rowe (FF  
15 96)) as a whole we determine that Sugano has shown that one skilled in the art  
16 would have had a reasonable expectation that non-glycosylated interferons  
17 would have at least some biological activity. To the extent Drs. Roberts' and  
18 Pitha-Rowe's testimony conflict as to whether one skilled in the art would have  
19 expected hFIF expressed in *E. coli* to have activity, we credit Dr. Roberts'  
20 testimony. Dr. Roberts' testimony is supported by a number of contemporaneous

---

<sup>23</sup> On cross-examination, Dr. Roberts stated that he did not consider himself to be an expert in the glycosylation of proteins. (Exh. 1134 at 8:17-9:10). Given Dr. Roberts' background and the published papers he has considered, we find him qualified to provide the opinion of one having ordinary skill in the art as of March 1980.

1 publications, including the review article by Stewart. On the other hand, Dr.  
2 Pitha-Rowe's testimony, while perhaps raising some questions about some of the  
3 data reported in the publications discussed by Dr. Roberts in his testimony, does  
4 not overcome what the evidence shows to have been an acceptance in the art  
5 that non-glycosylated interferons would have been expected to have at least  
6 some form of biological activity.

7 Sugano has met its burden of showing that its '931 JP application  
8 described and enabled embodiment within the scope of the Count 2 in each  
9 interference. Thus, in each interference, we GRANT Sugano motion 4.

10 D. Patentability Motions

11 In each interference, we grant Sugano's motion for benefit of the '931 JP  
12 application. In each interference, Goeddel's earliest alleged date of conception is  
13 later than the filing date of the '931 JP application. Accordingly, Goeddel cannot  
14 prevail on priority.

15 Goeddel has filed a number of motions alleging that some of the involved  
16 Sugano claims are unpatentable over prior art ('334 at Papers 29-31 and '337 at  
17 Papers 41 and 42),<sup>24</sup> the natural human chromosome ('334 at Paper 28 and '337  
18 at Paper 40) and or for lack of utility ('334 at Paper 34 and '337 at Paper 40). We  
19 need not decide those motions to complete our determination of priority. We  
20 note that:

---

<sup>24</sup> In 105,334, Goeddel motions 4 and 5 were deferred and in 105,337  
Goeddel motion 3 and 4 were deferred ('334 at Paper 54 and '337 at Paper 60).  
These motions were filed but no oppositions or replies were filed.

1           (1)     neither any motion individually, nor the combination of the motions,  
2     attack the patentability of all of the involved Sugano claims in either interference.  
3     Thus, even if we granted each Goeddel motion attacking patentability, Sugano  
4     would have claims directed to mature hFIF and encoding DNA remaining in the  
5     interference,

6           (2)     a decision on the patentability of the attacked Sugano claims is not  
7     necessary to a determination of priority,

8           (3)     the Sugano claims that Goeddel contends are unpatentable are not  
9     part of the substitute Count of either interference and thus deciding the  
10    patentability motions could not have the effect of changing the Count,

11          (4)     in interference 105,334, at least as to the prior art challenges,  
12    Goeddel has an alternative remedy under 35 USC § 302, and

13          (5)     in interference 105,337, the Board will recommend that the  
14    Examiner, upon the resumption of *ex parte* prosecution, consider the motions  
15    filed by Goeddel that attack the patentability of the Sugano claims (as well as any  
16    Sugano oppositions and Goeddel replies). Bd.R. 127(c).

17           In each interference, Sugano motions 1 through 3 have been deferred.  
18    ('334 at Paper 47 and 54 and 337 at Papers 51 and 60). Since judgment will be  
19    entered against Goeddel in each interference, we need not and do not decide  
20    these deferred motions.

21           E.     Miscellaneous Motions

22           In each interference, Goeddel moves to exclude the following exhibits:  
23    2017, 2165, 2167, and 2171. ('334 at Paper 82 and '337 at Paper 85). Because

1 we did not rely upon these exhibits as a basis for our decision, we need not and  
2 do not decide the Goeddel motion to exclude.

3 In each interference, Sugano moves to exclude Goeddel exhibits 1150-  
4 1170, 1172-1178, 1180, and 1181 and the Goeddel replies that rely upon the  
5 exhibits (i.e., Goeddel Replies 1, 7, and 8 in 105,334 and Goeddel Replies 1 and  
6 7 in 105,337). ('334 at Paper 86 and '337 at Paper 89 ). Because we did not rely  
7 upon these exhibits as a basis for our decision, we need not and do not decide  
8 the Sugano motion to exclude.

## 9 **V. Summary**

10 In each interference:

11 (1) we grant the Goeddel motion to substitute Count 2 for Count 1,

12 (2) we deny the Goeddel motions for judgment based on a lack of  
13 written description or enablement,

14 (3) we dismiss all other Goeddel motions, and

15 (4) we grant Sugano's motion for benefit of the '931 JP application.

16 We dismiss all other Sugano motions. Because Goeddel has not alleged a date  
17 that is prior to Sugano's earliest accorded benefit date, Goeddel cannot prevail in  
18 the interference.

19 The interference will be redeclared with Count 2 and Sugano designated  
20 as senior party.<sup>25</sup> Judgment on priority will be entered against Goeddel in each  
21 interference. Bd. R. 127(a).

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<sup>25</sup> The parties will not be given an opportunity to provide updated priority statements as to Count 2 since Count 2 is narrower in scope than Count 1.

1     **VI.     ORDER**

2             Upon consideration of the record, it is

3                     ORDERED that in interference 105,334:

4                             Goeddel Motion 1 is GRANTED;

5                             Goeddel Motions 2 through 5 and 8 are DISMISSED;

6                             Goeddel Motions 6 and 7 are DENIED;

7                             The Goeddel miscellaneous motion to exclude evidence is  
8 dismissed;

9                             Sugano Motion 1-3 are DISMISSED;

10                            Sugano Motion 4 is GRANTED;

11                            The Sugano miscellaneous motion to exclude evidence is  
12 dismissed;

13                            FURTHER ORDERED that in interference 105,337:

14                            Goeddel Motion 1 is GRANTED;

15                            Goeddel Motions 2 through 4 and 7 are DISMISSED;

16                            Goeddel motions 5 and 6 are DENIED;

17                            The Goeddel miscellaneous motion to exclude evidence is  
18 dismissed;

19                            Sugano Motions 1-3 are DISMISSED;

20                            Sugano Motion 4 is GRANTED;

21                            The Sugano miscellaneous motion to exclude evidence is  
22 dismissed.

23

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Paper 112  
Filed: 29 September 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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DAVID V. **GOEDEL**,  
And ROBERTO CREA

Junior Party  
(Patent 5,460,811),  
v.

HARUO **SUGANO**,  
MASAMI MURAMATSU, and TADATSUGU TANIGUCHI

Senior Party  
(Application 08/463,757).

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Patent Interference No. 105,337)  
(Technology Center 1600)

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*Before:* RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P.  
TIERNEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge.*

**Decision – Motions – Bd.R. 125(a)**

1   **I. Introduction**

2           Related interferences 105,334 ('334) and 105,337 ('337) were declared on  
3   25 August 2006. ('334 and '337 at Paper 1). Both parties have filed non-priority  
4   motions.

5           Oral argument on the non-priority motions was held on 10 October 2007.  
6   ('334 at Paper 105 and '337 at Paper 108). Thomas Friebe argued on behalf of  
7   Goeddel and Nels Lippert argued on behalf of Sugano.

8   **II. Background**

9           The subject matter of interference 105,334 is DNA coding for human  
10   fibroblast  $\beta_1$  interferon (hFIF). The subject matter of interference 105,337 is the  
11   polypeptide hFIF..

12          The parties agree that the "precursor form" of hFIF is a 187 amino acid  
13   protein containing a 21 amino acid "presequence" that is attached to the amino  
14   terminus of the 166 amino acid "mature" form of hFIF. The parties further agree  
15   that the first thirteen amino-terminal amino acids of the mature form of hFIF were  
16   known in the art as of February 1980. The parties also agree that the Count of  
17   each interference should be limited to either the mature form of hFIF, i.e., the 166  
18   amino acid mature form that lacks the 21 amino acid "presequence" ('337) or the  
19   DNA encoding the mature form of hFIF ('334). It appears that, a previous  
20   interference, i.e., interference 101,096, dealt with the issue of priority as to the  
21   precursor form of hFIF.

22          In interference 105,334, Goeddel has filed eight substantive motions.  
23   Seven of these motions are motions for judgment that the Sugano claims are



1 unpatentable over prior art or under 35 USC §101 and §112. One of these seven  
2 motions is a motion for judgment that the Sugano claims are unpatentable for  
3 failure to comply with the written description requirement of 35 USC §112, ¶1,  
4 and another is a motion for judgment that the Sugano claims are unpatentable for  
5 failure to comply with the enablement requirement of 35 USC §112, ¶1. Goeddel  
6 also has filed a motion seeking to substitute proposed Count 2 for Count 1.

7 We deny each of the Goeddel motions for judgment that the Sugano  
8 claims are unpatentable for failing to comply with the written description or  
9 enablement requirement. We grant the Goeddel motion to substitute a Count.  
10 We dismiss the other Goeddel motions.

11 In interference 105,337, Goeddel has filed seven substantive motions. Six  
12 of these motions are motions for judgment that the Sugano claims are  
13 unpatentable over prior art or under 35 USC §101 and §112. One of these six  
14 motions is a motion for judgment that the Sugano claims are unpatentable for  
15 failure to comply with the written description requirement of 35 USC §112, ¶1,  
16 and another is a motion for judgment that the Sugano claims are unpatentable for  
17 failure to comply with the enablement requirement of 35 USC § 112, ¶1.  
18 Goeddel also has filed a motion seeking to substitute proposed Count 2 for  
19 Count 1.

20 Key issues in the Goeddel motions we have considered are (1) whether  
21 Goeddel has shown that the current Count in each interference encompasses  
22 more than the DNA coding for ('334), or the polypeptide having ('337), the amino  
23 acid sequence of mature hFIF; (2) whether Goeddel has shown that Sugano did

1 not have possession of the DNA coding for, or the polypeptide having, the amino  
2 acid sequence of mature hFIF , and (3) whether Goeddel has shown that at the  
3 time of the filings of the applications underlying the involved Sugano patents  
4 ('334) and involved Sugano application ('337), one skilled in the art would not  
5 have been able to make and use the DNA coding for, and the polypeptide  
6 having, the amino acid sequence of mature hFIF. We determine that the current  
7 Counts do encompass more than is properly the subject matter of each  
8 interference and thus grant the Goeddel motions to substitute a Count. Goeddel  
9 has not shown that Sugano failed to provide written description and enablement  
10 for the claimed subject matter and deny the Goeddel motions seeking judgment  
11 against Sugano on those bases. All other Goeddel motions are dismissed.

12 In each interference, Sugano has filed four substantive motions, three of  
13 which have been deferred. The single Sugano motion presently before us is a  
14 motion seeking priority benefit of Sugano Japanese patent application no.  
15 33931/1980 filed 19 March 1980. ('931 JP application).

16 The key issue in the single Sugano motion that is before us in each  
17 interference, is whether, in its '931 JP application, Sugano provided sufficient  
18 description of, and enabling disclosure for, the mature form of hFIF and the DNA  
19 coding for the mature form. We have determined that Sugano has provided  
20 written description and enablement for the mature form of hFIF, and the DNA  
21 coding for the mature form of hFIF, in the '931 JP application. We grant the  
22 Sugano motions for benefit. All other Sugano motions are dismissed.

Because Sugano has established an earlier constructive reduction to practice in its '931 JP application, we have determined that Sugano is entitled to priority benefit of that application. Goeddel has not alleged a date in its priority statement that is prior to the filing date of the '931 JP application. Accordingly, Goeddel cannot prevail in the interference and judgment shall be entered against Goeddel in a separate paper.

Interference 105,334

In interference 105,334, Goeddel filed the following motions:

1. A motion to substitute proposed Count 2 for Count 1 (Paper 27).  
Sugano opposed. (Paper 57).

2. A motion for judgment that the Sugano claims are unpatentable under 35 USC §101 in view of the human chromosome. (Paper 28). Sugano opposed. (Paper 58).

3. Three motions for judgment that the Sugano claims are unpatentable over prior art (Papers 29-31), two of which have been deferred. (Paper 54). Sugano opposed as to the non-deferred motion. (Paper 59).

4. A motion for judgment that the Sugano claims lack enablement under 35 USC §112, ¶1. (Paper 32). Sugano opposed. (Paper 60).

5. A motion for judgment that the Sugano claims lack written description under 35 USC §112, ¶1. (Paper 33). Sugano opposed. (Paper 61).

6. A motion for judgment that the Sugano claims are unpatentable for lack of utility under 35 USC §101 and §112, ¶1. (Paper 34). Sugano opposed. (Paper 62).

1           7.       A motion to exclude certain evidence relied upon by Sugano.  
2       (Paper 82). Sugano opposed. (Paper 90).

3 Sugano filed the following motions.

1. Two motions for judgment that the Goeddel claims are unpatentable over prior art. (Paper 36 and 37). Both motions have been deferred. (Paper 54).

7           2.       A motion for judgment that the Goeddel claims are unpatentable  
8       under 35 USC §102(f). (Paper 38). This motion has been deferred. (Paper 47).<sup>1</sup>

9           3.     A motion to be accorded priority benefit of an earlier filed  
10 application. (Paper 39). Goeddel opposed. (Paper 55).

11           4.       A motion to exclude certain evidence relied upon by Goeddel in  
12       certain Goeddel replies. (Paper 86). Goeddel opposed. (Paper 89).

13 Interference 105,337

14 In interference 105,337, Goeddel filed the following motions:

15           1.       A motion to substitute proposed Count 2 for Count 1 (Paper 39).  
16   Sugano opposed. (Paper 63).

17           2.       A motion for judgment that the Sugano claims are unpatentable  
18   under 35 USC §101 in view of the human chromosome. (Paper 40). Sugano  
19   opposed. (Paper 64).

<sup>1</sup> A motion based on third party derivation was authorized to be filed during the non-priority phase of the interference. Because the motion filed by Sugano was not based on third party derivation but alleged derivation from Sugano, further briefing was deferred. (Paper 47 at 3). Since judgment will be entered against Goeddel, the issue of derivation is moot.

1           3.     Two motions for judgment that the Sugano claims are unpatentable  
2 over prior art. (Papers 41 and 42), both of which have been deferred.  
3 (Paper 60).

4           4.     A motion for judgment that the Sugano claims lack enablement  
5 under 35 USC §112, ¶1. (Paper 43). Sugano opposed. (Paper 65).

6           5.     A motion for judgment that the Sugano claims lack written  
7 description under 35 USC §112, ¶1. (Paper 44). Sugano opposed. (Paper 66).

8           6.     A motion for judgment that the Sugano claims are unpatentable for  
9 lack of utility under 35 USC §101 and §112, ¶1. (Paper 45). Sugano opposed.  
10 (Paper 67).

11          7.     A motion to exclude certain evidence relied upon by Sugano.  
12 (Paper 85). Sugano opposed. (Paper 94).

13               Sugano filed the following motions.

14          1.     Two motions for judgment that the Goeddel claims are  
15 unpatentable over prior art. (Paper 32 and 33). Both motions have been  
16 deferred. (Paper 60).

17          2.     A motion for judgment that the Goeddel claims are unpatentable  
18 under 35 USC §102(f). (Paper 34). This motion has been deferred. (Paper 51).<sup>2</sup>

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<sup>2</sup>     A motion based on third party derivation was authorized to be filed during the non-priority phase of the interference. Because the motion filed by Sugano was not based on third party derivation but alleged derivation from Sugano, further briefing was deferred. (Paper 51 at 3). Since judgment will be entered against Goeddel, the issue of derivation is moot.

1           3.     A motion to be accorded priority benefit of an earlier filed  
2 application. (Paper 32). Goeddel opposed. (Paper 61).

3           4.     A motion to exclude certain evidence relied upon by Goeddel in  
4 certain Goeddel replies. (Paper 89). Goeddel opposed. (Paper 92).

5     **III.     Findings of fact**

6           The record supports the following findings of fact by a preponderance of  
7 the evidence.

8                                     Interference 105,334

9           1. Interference 105,334 was declared on 25 August 2006. (Declaration,  
10 Paper 1).

11          2. Sugano is involved in interference 105,334 on the basis of the following  
12 two patents:

13           5,514,567, issued on 7 May 1996 from application  
14 08/400,179, filed 6 March 1995

15  
16           5,326,859, issued on 5 July 1994 from application  
17 06/201,359, filed 27 October 1980

18  
19     (*Id. at* 3).

20  
21          3. The inventors in each patent are said to be Haruo Sugano, Masami  
22 Muramatsu, and Tadatsugu Taniguchi.

23          4. Sugano has identified the real parties in interest as “Judicial Foundation,  
24 Japanese Foundation for Cancer Research,” said to be an assignee, and  
25 “Kyowa Hakko Kogyo Co., Ltd.,” “Toray Industries, Inc., and “Schering  
26 Aktiengesellschaft,” said to be licensees. (Paper 6).

1 5. Goeddel is involved in the interference on the basis of its application  
2 07/374,311, filed 30 June 1989. (Paper 1 at 4).

3 6. The inventors in the application are said to be David V. Goeddel and  
4 Roberto Crea.

5 7. Goeddel has identified the real party in interest as Genentech, Inc. ('334  
6 at Paper 11).

7 8. The count of the interference, Count 1, is as follows:

8 Claim 9 of Sugano, 5,514,567  
9 or  
10 claim 6 of Sugano, 5,326,859  
11 or  
12 claim 35 of Goeddel, 07/374,31  
13 (Paper 1 at 4).

14 9. Claim 9 of Sugano patent 5,514,567 ('567) is as follows:

15 A recombinant plasmid wherein a DNA which codes for the amino  
16 acid sequence:  
17  
18 Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
19 Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
20 Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu  
21 Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
22 Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
23 Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
24 Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe  
25 Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
26 Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
27 Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
28 Leu Thr Gly Tyr Leu Arg Asn  
29  
30 is inserted in a vector DNA.  
31  
32 (Sugano clean copy of claims, Paper 5).

1  
2 10. Claim 6 of Sugano patent 5,326,859 ('859) is as follows:

3 A DNA consisting essentially of a DNA which codes for mature  
4 human fibroblast interferon polypeptide having the amino acid  
5 sequence:

6  
7  
8 Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe Gln  
9 Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys Leu  
10 Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu Gln  
11 Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu Gln  
12 Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp Asn  
13 Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile Asn  
14 His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe Thr  
15 Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly Arg  
16 Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp Thr  
17 Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg Leu  
18 Thr Gly Tyr Leu Arg Asn.

19  
20 (*Id.*).

21  
22 11. Claim 35 of Goeddel application 07/374,311 is as follows:

23  
24 A DNA consisting essentially of a DNA which codes for mature  
25 human fibroblast interferon polypeptide having the amino acid  
26 sequence:

27  
28 Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
29 Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
30 Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu  
31 Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
32 Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
33 Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
34 Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe  
35 Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
36 Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
37 Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
38 Leu Thr Gly Tyr Leu Arg Asn.

39  
40 (Goeddel clean copy of claims, Paper 9).

41  
42 12. The parties were accorded the following benefit for Count 1:

43 Sugano:



1 US 06/389,922, filed 18 June 1982

2 US 06/201,359, filed 27 October 1980, issued as involved  
3 patent 5,326,859 on 5 July 1994<sup>3</sup>

4

5

6

7 Goeddel:

8 US 06/879,712, filed 27 June 1986

9 US 06/291,892, filed 11 August 1981

10 US 06/190,799, filed 25 September 1980

11 (Paper 1 at 5).

12 13. Claims 9-14, 18-20, 24-27, and 29 of Sugano's '567 patent, claims 1 and

13 6-9 of Sugano's '859 patent and claims 25-52 of Goeddel's involved

14 application, are designated as corresponding to Count 1. (*Id.*).

15 14. According to Goeddel's priority statement (Bd. R. 204 (a)(2)), as to the

16 subject matter of Count 1, "Party Goeddel's earliest corroborated

17 conception was in the United States on May 7, 1980". (Paper 25).

18 Interference 105,337

19 15. The interference was declared on 25 August 2006. (Declaration, Paper 1).

20 16. Sugano is involved in interference 105,337 on the basis of its application

21 08/463,757, filed 5 June 1995. (*Id. at 3*).

22 17. The inventors in the application are said to be Haruo Sugano, Masami

23 Muramatsu, and Tadatsugu Taniguchi.

---

<sup>3</sup> In application 06/201,359, Sugano claimed a priority date of 19 March 1980 based on the '931 JP application. 35 USC §119(a). (Inventor declaration in Exh. 2009). Sugano was not accorded benefit of the '931 JP application in the Declaration of Interference.

1 18. Sugano has identified the real parties in interest as “Judicial Foundation,  
2 Japanese Foundation for Cancer Research,” said to be an assignee, and  
3 “Kyowa Hakko Kogyo Co., Ltd.,” “Toray Industries, Inc.,” and “Schering  
4 Aktiengesellschaft,” said to be licensees. (Paper 6).

5 19. Goeddel is involved in the interference on the basis of its patent  
6 5,460,811, issued on 24 October 1995 from application 07/365,284, filed  
7 12 June 1989.

8 20. The Goeddel inventors are said to be David V. Goeddel and Roberto  
9 Crea.

10 21. Goeddel has identified the real party in interest as Genentech, Inc. (Paper  
11 13).

12 22. The count of the interference, Count 1, is as follows:

13  
14 Claim 31 of Sugano, 08/463,757  
15  
16 or  
17  
18 claim 2 of Goeddel, 5,460,811.  
19

20 (Paper 1 at 4).

21 23. Claim 31 of application 08/463,757 is as follows:

22 Recombinant human fibroblast  $\beta$ 1 interferon having the  
23 amino acid sequence:

24  
25 Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe  
26 Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys  
27 Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu  
28 Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu  
29 Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp  
30 Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile  
31 Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Glu Asp Phe

1 Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Tyr Gly  
2 Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp  
3 Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg  
4 Leu Thr Gly Tyr Leu Arg Asn.  
5

6 ( Sugano clean copy of claims, Paper 5).  
7

8 24. Claim 1 (from which claim 2 depends) and claim 2 of Goeddel 5,460,811

9 are as follows:

10 (claim 1) A composition comprising water and a  
11 nonglycosylated polypeptide having the amino acid sequence of a  
12 mature human fibroblast interferon, said nonglycosylated  
13 polypeptide having a total of 165 or 166 amino acids and said  
14 composition being free of any glycosylated human fibroblast  
15 interferon.  
16

17 (claim 2)The composition of claim 1, said nonglycosylated  
18 polypeptide having the amino acid sequence

19  
20 X-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser-Asn-Phe-  
21 Gln- Cys-Gln-Lys-Leu-Leu-Trp-Gln-Leu-Asn-Gly-Arg-Leu-Glu-Tyr-  
22 Cys-Leu- Lys-Asp-Arg-Met-Asn-Phe-Asp-Ile-Pro-Glu-Glu-Ile-Lys-  
23 Gln-Leu-Gln- Gln-Phe-Gln-Lys-Glu-Asp-Ala-Ala-Leu-Thr-Ile-Tyr-  
24 Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-  
25 Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-  
26 Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-  
27 Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-  
28 Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-  
29 Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-  
30 Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn,  
31

32 wherein X is H or Met.  
33

34 (Goeddel clean copy of claims, Paper 10).  
35

36 25. The parties were accorded the following priority benefit as to Count 1:

37 Sugano:

38  
39 US 08/400,179, filed 6 March 1995,  
40 issued as 5,514,567 on 7 May 1996  
41

1 US 06/389,922, filed 18 June 1982

2 US 06/201,359, filed 27 October 1980,  
3 Issued as 5,326,859 of 5 July 1994<sup>4</sup>  
4

5 Goeddel:

6 US 06/889,722, filed 28 July 1986

7 US 06/291,892, filed 11 August 1981

8 US 06/190,799, filed 25 September 1980

9 (Paper 1 at 4-5).

10 26. Sugano claims 4, 30, 31, 36, 39-44, 46, and 48-50 and Goeddel  
11 claims 1-6 were designated as corresponding to Count 1. (Paper 1 at 4).

12 27. According to Goeddel's priority statement (Bd. R. 204 (a)(2)), as to the  
13 subject matter of Count 1, "Party Goeddel's earliest corroborated  
14 conception was in the United States on May 7, 1980". (Paper 30).

15 Substitute Count

16 28. The parties agree that the Count in each interference should be limited to  
17 DNA encoding or the polypeptide having only the 166 amino acids of  
18 mature hFIF. (Transcript, '334, Paper 108 and '337, Paper 111 at 7:11-15  
19 and 32:1-7).

20 29. According to the parties, in a previous interference,<sup>5</sup> Sugano prevailed on  
21 a Count that was directed to "A DNA which consists essentially of a DNA

---

<sup>4</sup> In application 06/201,359, Sugano claimed a priority date of 19 March 1980 based on the '931 JP application. 35 USC §119(a). (Inventor declaration in Exh. 2009). Sugano was not accorded benefit of the '931 JP application in the Declaration of Interference

which codes for a human fibroblast interferon-beta polypeptide.”

(Transcript at 13:13-15 and, e.g., '334, Paper 58 at 9).

30. It does not appear that the Count was construed expressly during the interference or on appeal. (Transcript at 13:8-16 and, e.g., '334, Paper 58 at 8-9).

31. It is our understanding that “human fibroblast interferon-beta polypeptide” is a polypeptide having the complete 187 amino acids of hFIF.<sup>6</sup> (See *also*, *e.g.*, ‘334, Paper 55 at 7-8).

32. For interference 105,334, Goeddel proposed substitute Count 2 is:

A DNA encoding a mature human fibroblast interferon having a total of 166 amino acids of the sequence:

[listing of the 166 amino acids of mature human fibroblast interferon]

and unaccompanied by a human fibroblast interferon presequence.

(‘334, Paper 27 at 2).

33. In interference 105,337, Goeddel proposed substitute Count 2 is:

Claim 49 of Sugano, 08/463,757

or

Claim 2 of Goeddel, 5,460,811.

(‘337, Paper 39 at 3).

<sup>5</sup> The Board's decision was affirmed in *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

<sup>6</sup> We note that the Board's decision holding that Sugano was entitled to benefit of the '931 JP application was affirmed because, *inter alia*, the application set forth "the complete and correct nucleotide sequence of a DNA coding for  $\beta$ -IF." *Fiers* at 1171.

1 34. Proposed Count 2 differs from Count 1 in that involved Sugano claim 49 is  
2 substituted for involved Sugano claim 31.

3 35. Claim 49 of Sugano 08/463,757 is as follows:

4 A composition comprising water and a nonglycosylated mature  
5 human fibroblast interferon polypeptide having a total of 166 amino  
6 acids and the following amino acid sequence

7

8 [listing of the 166 amino acids of mature human fibroblast  
9 interferon]

10

11 ...said composition being free of any glycosylated human fibroblast  
12 interferon.

13

14 ('337, Paper 5).

15

Written Description and Enablement

16 36. The involved Sugano claims include within their scope, DNA coding for  
17 ('334), and the polypeptide having ('337), the amino acid sequence of the  
18 mature form of hFIF.

19 37. The Sugano involved specifications disclose the 166 amino acid sequence  
20 of the mature form of hFIF as a sequence embedded within the 187-amino  
21 acid sequence of the precursor form of hFIF at Table 5. ('337, Paper 44 at  
22 Goeddel Statement of Material Fact (smf) 6) (Exh. 2010 at 16-18, Exh.  
23 2001 at 11-12 and Exh. 2002 at 11-13).

24 38. Table 5 of the Sugano specifications is reproduced below:

Table 5

Met Ile Asn Lys Cys Leu Leu Gly Ile Ala Leu Leu Leu Cys Phe Ser Thr Thr Ala Leu Ser Met Ser Lys  
 GTC AAC ATG ACC AAC AAG TGT CTC CTC CAA ATT GCT CTC CTG TTG TGC TTC TCC ACT ACA GCT CTT TCC ATG ACC TAC  
 CAG TTG TAC TGG TTG TTC ACA GAG GAG GTT TAA CGA GAG GAC AAC ACG AAG AGG TGA TGT CGA GAA AGG TAC TCG ATG  
 20 40 60  
 Asn Lys Leu Gly Phe Leu Glu Arg Ser Ser Asn Phe Gly Cys Gly Lys Leu Leu Thr Gly Leu Asn Gly Arg Leu Gly  
 AAC TTG CTT GGA TTC CTA CAA AGA AGC ACC AAT TTT CAG TGT CAG AAG CTC CTG TGG CAA TTG AAT GGG AGG CTT GAA  
 TTG AAC GAA CCT AAG GAT GTT TCT TCG TCG TTA AAA GTC ACA GTC TTC GAG GAC ACC GTT AAC TTA CTT TCC GAA CTT  
 80 100 120 140  
 Lys Cys Leu Lys Asn Arg Met Asn Phe Asp Ile Phe Gly Gly Ile Lys Gly Leu Gly Gly Phe Gly Lys Gly Asn Ala  
 TAT TGC CTC AAG GAC AGG ATG AAC TTT GAC ATC CCT GAG GAG ATT AAG CAG CTG CAG CAG TTC CAG AAG GAG GAC GCC  
 ATA ACG GAG TTC CTG TCC TAC TTG AAA CTG TAG GGA CTC CTC TAA TTC GTC GAC GTC GTC AAG GTC TTC CTC CTG CCG  
 160 180 200 220  
 Ala Leu Thr Ile Lys Glu Met Leu Glu Asn Ile Phe Ala Ile Phe Arg Gly Asn Ser Ser Ser Thr Gly Lys Asn Gly  
 GCA TTG ACC ATC TAT GAG ATG CTC CAG AAC ATC TTT GCT ATT TTC AGA CAA GAT TCA TCT AGC ACT GGC TGG AAT GAG  
 CGT AAC TGG TAG ATA CTC TAC GAG GTC TTG TAG AAA CGA TAA AAG TCT GTT CTA AGT AGA TCG TGA CCG ACC TTA CTC  
 240 260 280 300  
 Thr Ile Val Glu Asn Leu Leu Ala Ser Val Lys His Gly Ile Asn His Leu Lys Thr Val Leu Glu Gly Lys Leu Gly  
 ACT AIT GTT GAG AAC CTC CTG GCT AAT GTC TAT CAT CAG ATA AAC CAT CTG AAG ACA GTC CTG GAA GAA AAA CTG GAG  
 TGA TAA CAA CTC TTG GAG GAC CGA TTA CAG ATA GTA GTC TAT TTG GTA GAC TTC TGT CAG GAC CTT CTT TTT GAC CTC  
 320 340 360 380  
 Lys Glu Asp Phe Thr Asn Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Thr Thr Gly Asn Ile Leu His Lys Leu  
 AAT GAA GAT TTC ACC AGG GGA AAA CTC ATG ACC AGT CTG CAC CTG AAA AGA TAT TAT GGG AGG ATT CTG CAT TAC CTG  
 TTT CTT CTA AAG TGG TCC CCT TTT GAG TAC TCG TCA GAC GTC GAC TTT TCT ATA ATA CCC TCC TAA GAC GTA ATG GAC  
 400 420 440 460  
 Lys Ala Lys Glu Thr Ser His Cys Ala Thr Thr Ile Val Asn Val Gly Ile Leu Asn Asn Phe Thr Phe Thr Asn Asn  
 AAG GCC AAG GAG TAC AGT CAC TGT GCC TGG ACC ATA GTC AGA GTG GAA ATC CTA AGG AAC TTT TAC TTC ATT AAC AGA  
 TTC CCG TTC CTC ATG TCA GTG ACA CCG ACC TGG TAT CAG TCT CAC CTT TAG GAT TCC TTG AAA ATG AAG TAA TTG TCT  
 480 500 520 540  
 Leu Thr Gly Lys Leu Arg Asn  
 CTT ACA GGT TAC CTC CGA AAC TGA AGA TCT CCT AGC CTG TGC CTC TGG GAC TGG ACA ATT GCT TCA AGC ATT CTT CAA  
 GAA TGT CCA ATG GAG GCT TTG ACT TCT ASA GGA TCG GAC ACG GAG ACC CTG ACC TGT TAA CGA AGT TCG TAA GAA GTT  
 560 580 600 620  
 CCA GCA GAT GCT GTT TAA GTG ACT GAT GGC TAA TGT ACT GCA TAT GAA AGG ACA CTA GAA GAT TTT GAA ATT TTT ATT  
 GGT CGT CTA CGA CAA ATT CAC TGA CTA CCG ATT ACA TGA CGT ATA CTT TCC AGT GAT CTT CTA AAA CTT TAA AAA TAA  
 640 660 680 700  
 AAA TTA TGA GTT ATT TTT ATT TAT TTA AAT TTT ATT TTG GAA AAT AAA TTA TTT TTG GTG CAA AAG TCA AAA AAA  
 TTT AAT ACT CAA TAA AAA TAA ATA AAT TTA AAA TAA AAC CTT TTA TTT AAT AAA AAC CAC GTT TTC AGT TTT TTT  
 720 740 760

- 1
- 2 According to the involved specifications, Table 5 shows the base
- 3 sequence of the DNA which codes for human interferon polypeptide. (See
- 4 e.g., Exh. 2002 at 5:26-28).

1 39. According to the Sugano specifications, “the entire amino acid sequence  
2 for human fibroblast interferon (amino acids 1-166) and its putative signal  
3 peptide (amino acids -21 to -1)” is shown above the DNA sequences.  
4 (Exh. 2010 at 18, Exh. 2001, and 2002 at 15:1-4).

5 40. The first thirteen amino acids of the mature form of hFIF were reported in  
6 the art in February 1980 by Knight.<sup>7</sup>

7 41. The involved Sugano specifications state that “[i]t is important that in the  
8 sequence there exist without any error the base sequence (three base  
9 pairs) corresponding to the amino acid sequence from the amino-terminal  
10 to [the] 13<sup>th</sup> amino acid of the human fibroblast interferon reported by  
11 Knight...” and that “[t]his fact establishes that the #319-13 plasmid of the  
12 present invention has the human fibroblast interferon mRNA sequence.”  
13 (Exh. 2010 at 18, Exh. 2001 at 15:6-13 and Exh. 2002 at 15:5-11).

14 42. The Sugano specifications further state that “it is apparent from the data of  
15 the primary sequence that the plasmid encompasses the entire coding  
16 region of the protein of the above mRNA and probably the coding region  
17 of the signal peptide.” (Exh. 2010 at 18 and Exh. 2001 at 15:14-29 and  
18 Exh. 2002 at 15:12-16).

19 43. The Sugano specifications do not disclose a detailed method for  
20 expressing the mature form of hFIF in *E. coli*, that is, the 166 amino acid  
21 sequence absent the 21 amino acid signal peptide. (See, e.g., ‘337, Paper

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<sup>7</sup> Knight et al., *Science*, 207:525-526 (1980) (Exh. 1037).



1           63 at 3:12-16, acknowledging that plasmid #319-13 is not an expression  
2           plasmid and cannot produce recoverable amounts of hFIF.).

3           44. Goeddel concedes that as of 27 October 1980, one skilled in the art, given  
4           the sequence of Table 5 and the amino acid sequence of Knight, “should  
5           have been able to envision a DNA encoding *mature* hFIF having a *total* of  
6           166 amino acids and *unaccompanied* by the hFIF presequence.” (‘334,  
7           Paper 32 at 7 and ‘337, Paper 43 at 7, original emphasis).

8           45. Goeddel concedes that “[a]s of March 19, 1980, one of ordinary skill  
9           recognized that a DNA encoding the hFIF precursor would not be itself  
10          useful for expressing mature hFIF in *E. coli*” and that it was known that a  
11          DNA free “of [the] presequence would have to be inserted into an  
12          expression system.” (‘334, Paper 55 at 12-13 and ‘337, Paper 61 at 11).

13          46. Goeddel concedes that as of October 27, 1980, a method for tailoring the  
14          hFIF precursor gene to provide a DNA ending the mature form of hFIF  
15          having a total of 166 amino acids unaccompanied by the hFIF  
16          presequence and for the high-level expression of that tailored gene in a  
17          strain of *E. coli* had been developed and published (See, e.g., ‘337,  
18          Paper 66 at 18; Transcript at 5:13-6:5).

19          47. In particular, Goeddel concedes that David Goeddel disclosed the tailoring  
20          and high-level expression of a gene encoding the mature form of hFIF  
21          having a total of 166 amino acids and unaccompanied by a hFIF

1 sequence in a paper published 25 September 1980.<sup>8</sup> ('334, Paper 32 at  
2 14).

3 48. Goeddel points to other publications, published after October of 1980 but  
4 prior to July of 1994, reporting methods for expression of hFIF in *E. coli*.  
5 (Exh. 1108 (Second Declaration of Dr. Rik Derynck) at ¶127).

6 49. Each of the involved Sugano specifications states that the invention is "a  
7 DNA which codes for a polypeptide with interferon activity" that is to be  
8 expressed in *E. coli*. (See, e.g., Exh. 2001 at 1:40-53).

9 50. One skilled in the art during the relevant time frame "would have a Ph.D.  
10 degree or an equivalent degree, or be a highly skilled pre-doctoral fellow,  
11 with several years of research experience in molecular biology." (See,  
12 e.g., '337 at Paper 73, Goeddel admission to Sugano smf 38).

13 Benefit

14 51. Sugano filed Japanese patent application no. 33931/1980 on  
15 19 March 1980. ('931 JP application).

16 52. Sugano has filed a certified copy of the '931 JP application (Exh. 2012),  
17 an English translation of the '931 JP application, and an affidavit that the  
18 translation of the certified copy is accurate. (Exh. 2009 at 101-120).<sup>9</sup>

19 53. The '931 JP application is quite similar, but not identical, to the involved  
20 Sugano applications and patents.

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<sup>8</sup> Goeddel, *Nucl. Acids Res.* 8:4057 (1980) (Exh. 1012).

<sup>9</sup> Exhibit 2009, which is a copy of Sugano application 06/201,359, appears to be missing the page prior to that page numbered "102." However the original application file contains the missing page, i.e., page 100, which is the affidavit stating that the translation of the certified copy is accurate.

1 54. Table 5 of the '931 JP application and Table 5 of the involved Sugano  
2 application and patents appear to be the same except that the '931 JP  
3 application does not indicate by numbering the first amino acid in the  
4 Table 5 amino acid sequence and contains the word "Ter" after the last  
5 amino acid, i.e., "Asn".

6 55. The '931 JP application does not contain the statement that "the entire  
7 amino acid sequence for hFIF (amino acids 1-166) and its putative signal  
8 peptide (amino acids -21 to -1)" is shown in the DNA sequence at Table 5.

9 56. In March of 1980, "*E. coli* was known [by those skilled in the art] not to be  
10 able to glycosylate proteins faithfully." (Exh. 1108 at ¶ 36).

11 57. Dr. Thomas Roberts testified in the interference on behalf of Sugano.

12 58. Dr. Roberts testified that he has a Ph.D. in Biochemistry and Molecular  
13 Biology from Harvard University, that he was a post-doctoral fellow in the  
14 laboratory of Dr. Mark Ptashne at Harvard University between 1976 and  
15 December 1980, that he holds the position of Professor of Pathology at  
16 Harvard Medical School, and that he is the Chairman of the Division of  
17 Medical Sciences at Harvard University, the Faculty Dean at Harvard  
18 Medical School, and the Co-Chair of the Department of Cancer Biology at  
19 the Dana Farber Cancer Institute. (Exh. 2016, Robert Dec. at ¶¶2-4).

20 59. We find that Dr. Roberts is qualified to testify about technical issues  
21 relevant to the interferences.

1 60. Dr. Roberts points to publications in the art as early as 1978 suggesting  
2 “the use of bacteria to express eukaryotic proteins” and in particular  
3 interferon. (Exh. 2016 at ¶¶ 7-8).

4 61. Dr. Roberts points to over a dozen publications available in the art as early  
5 as 1978 showing that mammalian protein can be expressed in bacteria.  
6 (Exh. 2016 at ¶¶ 14-22).

7 62. Dr. Roberts points to an October 1979 Goeddel paper<sup>10</sup> showing direct  
8 expression (i.e., as opposed to expression of the precursor as a fusion  
9 protein) of human growth hormone in *E. coli*.

10 63. In that paper it is stated that the methods “are generally applicable to other  
11 polypeptides which are synthesized initially as inactive precursors and  
12 later processed, or for which full length cDNA transcripts are unavailable.”  
13 (Exh. 2021 at 548).

14 64. Dr. Roberts points to his own November 1979 paper<sup>11</sup> and a January 1980  
15 Emtage paper<sup>12</sup> which are said to provide additional examples (along  
16 with Goeddel) of a method of producing mammalian proteins in bacteria  
17 by directly expressing the gene. (Exh. 2016 at ¶ 25-26).

18 65. In the Roberts paper it is stated that “[o]ur experiments show that a  
19 message bearing a hybrid ribosome-binding site – i.e., sequences derived  
20 partly from the bacterium...and partly from the eukaryotic gene...– can be  
21 correctly translated into protein [and that] [t]his provides a rational

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<sup>10</sup> Goeddel et al, *Nature*, 281:544-548 (1979). (Exh. 2021)

<sup>11</sup> Roberts et al, *Proc. Natl. Acad. Sci. USA*, 76:5596-5600 (1979). (Exh. 2093).

<sup>12</sup> Emtage et al., *Nature*, 283:171-174 (1980). (Exh. 2094).

1 approach to the problem of obtaining expression of eukaryotic genes in  
2 bacteria.” (Exh. 2093 at 5600).

3 66. Dr. Roberts testified, and Goeddel admitted, that in view of the papers  
4 [discussed in the Roberts’ affidavit], one of skill in the art as of March 19,  
5 1980 would have at least known that certain eukaryotic genes can  
6 faithfully be expressed in bacteria, that certain bacterial promoters can  
7 drive expression of certain heterologous eukaryotic genes placed within  
8 certain plasmids, that certain mammalian proteins produced in bacteria  
9 can exhibit functionality, and that certain mammalian proteins can be  
10 transcribed and translated under the control of bacterial control elements,  
11 such that expression can be conducted without the need to make a  
12 bacterial-eukaryotic fusion protein, (‘337 at Paper 55 Goeddel response to  
13 Sugano smf 42; Exh. 2016 at ¶ 27).

14 67. Dr. Roberts points to a 1978 Backman paper<sup>13</sup> where it is stated that  
15 proteins can be directly expressed in *E. coli* using a method that “[i]n  
16 principle...should elicit high levels of expression in *E. coli* of any gene,  
17 whatever its source.” (Exh. 2016 at ¶ 31, Exh. 2095 at 65).

18 68. Dr. Roberts points to a February 1979 Roberts paper<sup>14</sup> which purports to  
19 describe a method that “in principle, will allow the same *lac* promoter to be  
20 placed at virtually any distance in front of a gene [such that] a native  
21 protein rather than a fusion protein” is produced. (Exh. 2016 at 32,  
22 Exh. 2096 at 760).

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<sup>13</sup> Backman et al, *Cell*, 13:65-71 (1978). (Exh. 2095).

<sup>14</sup> Roberts et al. *Proc. Natl. Acad. Sci. USA*, 76:760-764 (1979) (Exh. 2096).

1       69. The Roberts paper further teaches that “exonuclease III and S1 nuclease  
2       digestion used here should allow the placement of the promoter-  
3       containing fragment at virtually any distance upstream from most other  
4       genes...” (Exh. 2016 at ¶32 citing to pp. 760 and 764 of the Roberts  
5       paper).

6       70. We understand the methods discussed in the 1978 Backman and 1979  
7       Roberts papers are referred to by the parties as the “Ptashne lab  
8       methods”.

9       71. Dr. Roberts testified that:

10               [T]o make a human fibroblast interferon cDNA without any  
11       leader sequence, the cDNA can be digested with exonuclease III  
12       and S1 or other nucleases in order to generate a number of clones,  
13       one of which would have all of its presequence digested up to the  
14       mature ATG sequence. In fact, Goeddel’s U.S. Patent 4,342,832  
15       [issued on 3 August 1982<sup>15</sup>] explicitly teaches that exonuclease III  
16       and S1 can be used to remove leader sequences. After digestion,  
17       the clones are religated [sic], transformed into bacteria, and  
18       plasmid DNA can then be purified and analyzed, for example, by  
19       acrylamide gel analysis. Acrylamide gel analysis will allow the  
20       practitioner to determine which clones might have the entire  
21       presequence digested away. These clones can then be sequenced  
22       to confirm which ones only have the coding sequence for mature  
23       interferon, i.e., without coding sequence for the presequence.  
24       Alternatively, protein extracts from bacterial clones can be tested by  
25       immunoassays to identify potential clones that express the protein.  
26       Plasmids from these potential clones can be purified and  
27       sequenced to confirm which plasmids contain only the coding  
28       sequence for the mature interferon. Although this process can be  
29       labor intensive, the necessary methods....were well established in  
30       the art at least as of March 19, 1980.

31  
32       (Exh. 2016 at ¶¶ 46 and citing to ¶¶ 37-41).

---

<sup>15</sup> Because this Goeddel patent issued after March 19, 1980 we do not consider it to be part of the knowledge of one skilled in the art as of the filing date of the ‘931 JP application.

1 72. On cross-examination, Dr. Roberts testified that screening by size was a  
2 method available at the time of the publication of the Roberts February  
3 1979 paper. (Exh. 2181 at 34:11-35:4).

4 73. On cross-examination, Dr. Roberts testified that exonuclease III and S1  
5 would be used to make a clone that would have a “certainty” of achieving  
6 synthesis of the mature protein. (Exh. 2181 at 68:9-70:20).

7 74. On cross-examination, Dr. Roberts testified that using only the Ptashne  
8 lab methods available in 1980 (and not the beta galactosidase screening  
9 method of Guarente<sup>16</sup>), it would take a “[c]ouple of months” to be  
10 successful in expressing mature hFIF. (Exh. 2181 at 71:23-73:21).

11 75. Dr. Roberts pointed to papers published prior to March of 1980 reporting  
12 that non-glycosylated interferons expressed in bacteria would be expected  
13 to be active. (Exh. 2016 at ¶¶ 99-101).

14 76. Dr. Roberts testified that one skilled in the art, having reviewed the  
15 published art as of March of 1980, would have found it likely that  
16 completely non-glycosylated human interferons would maintain activity.  
17 (Exh. 2016 at ¶¶ 99-100).

18 77. Drs. Jean Content and Gail Lauer have also presented testimony in the  
19 interferences on behalf of Sugano.

20 78. Based on their testimony regarding their educational and professional  
21 backgrounds and education, we find Drs. Content and Lauer to be

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<sup>16</sup> Guarente et al, *Cell*, 20:543-553(1980) (Exh. 2132).

1 qualified to testify regarding technical issues relevant to the interferences.  
2 (Exh. 2145 at ¶¶ 2-5; Exh. 2146 at ¶¶ 2 and 3).

3 79. Drs. Content and Lauer testified that one skilled in the art could have used  
4 the Ptashne lab methods to make the DNA encoding mature hFIF as of  
5 19 March 1980 ( Exh. 2145 at ¶¶ 10 and 13; Exh. 2146 at ¶¶ 6 and 9).

6 80. Dr. Rik Dernyck testified in the interference on behalf of Goeddel.  
7 (Exh. 1108).

8 81. Dr. Dernyck testified that he has a Ph.D. in Molecular Biology from the  
9 University of Ghent, Belgium and was a predoctoral fellow/research  
10 associate with Dr. Walter Fiers. (Exh. 1108 at ¶ 2).

11 82. Dr. Dernyck testified that he is a Professor in the Department of Growth  
12 and Development and the Department of Cell and Tissue Biology at the  
13 University of California at San Francisco, that he is the co-director of the  
14 UCSF Institute for Regeneration Medicine and Director of its Program in  
15 Craniofacial and Mesenchymal Biology, and that he has conducted  
16 research in molecular biology and recombinant DNA technology and  
17 worked in the molecular biology departments at Genentech, Inc., the real  
18 party in interest for Goeddel. (Exh. 1108 at ¶¶ 3-5)

19 83. We find Dr. Dernyck to be qualified to testify regarding technical issues  
20 relevant to the interferences.

21 84. Dr. Dernyck testified that one skilled in the art, given the sequence of  
22 Table 5 and the amino acid sequence of Knight, both disclosed in the  
23 '931 JP application, should have been able to envision a DNA encoding



1 mature hFIF having a total of 166 amino acids and unaccompanied by the  
2 hFIF presequence. (Exh. 1108 at ¶ 59).

3 85. Dr. Dernyck acknowledged published reports in the art showing  
4 expression of mammalian proteins in *E. coli*, however, Dr. Dernyck  
5 testified that:

6 The observation, e.g., that a particular protein is stable in *E.*  
7 *coli* or that a particular protein can be expressed in *E. coli* was not  
8 predictive of successful expression of another selected protein.  
9 The reports discussed....above therefore would have been  
10 considered by those of ordinary skill to be more of a collection of  
11 anecdotal reports than a coherent body of art.

12  
13 (Exh. 1108 at ¶ 53).

14 86. Dr. Dernyck acknowledged that the “Ptashne [lab] methods” would yield  
15 the “desired clones” but with such low frequency that, given screening  
16 techniques available as of October of 1980, the “identification of rare  
17 isolates expressing mature human fibroblast interferon.....within an  
18 immense population of clones would have been unduly burdensome or  
19 impossible....” (Exh. 1108 at ¶ 83).

20 87. Dr. Dernyck testified further that “[t]his conclusion is supported by the  
21 actual frequency ultimately reported, in October 1980 from the Ptashne  
22 lab, i.e., desired clones were found at a frequency of 0.01%.” (Exh. 1108  
23 at ¶ 83).

24 88. Dr Dernyck points to “a later publication from the same [Ptashne]  
25 laboratory”, i.e., the Guarente paper, that is said to have provided for  
26 better screening methods, i.e., the  $\beta$ -galactosidase screening method.  
27 (Exh. 1108 at ¶ 61).

1       89.       Sugano points to a statement said to have been given by Dr.  
2       Dernyck in an EPO opposition proceeding in 1996 indicating that Dr.  
3       Dernyck  
4       pursued this goal [of expressing hFIF in E. coli] with the methodology  
5       available to us at that time, and no new technology was required to  
6       achieve the expression of IFN-  $\beta$ , which we accomplished about two  
7       months after obtaining possession of the full length cDNA encoding it [in  
8       late February of 1980].  
9  
10       ('337, Paper 77 at 5 and Exh. 2144 at ¶¶ 4-5).  
11       90. On cross-examination, Dr. Dernyck confirmed that he made the statement  
12       and that his understanding was:  
13       IFN-B is a polypeptide having interferon activity, and  
14       he had methodology available to him in the lab that others did not have.  
15       (Exh. 2162 at 55:9-61:6).  
16       91. Dr. Paula Pitha-Rowe testified in the interference on behalf on Goeddel.  
17       (Exh. 1080).  
18       92. Dr. Pitha-Rowe testified that she has a Ph.D. in Biochemistry from the  
19       Academy of Science in Prague, Czechoslovakia and that she has been  
20       working and publishing in the field of interferons since 1971. (Exh. 1080  
21       at ¶¶ 2-3).  
22       93. Dr. Pitha-Rowe testified that she is a professor of oncology with a joint  
23       appointment in molecular biology at Johns Hopkins University School of  
24       Medicine. (Exh. 1080 at ¶ 4).  
25       94. We find that Dr. Pitha-Rowe is qualified to testify about issues relevant to  
26       this interference.

1 95. Dr. Pitha-Rowe testified that, despite papers published prior to March of  
2 1980 reporting that non-glycosylated interferons expressed in bacteria  
3 would be expected to be active, “researchers as of March 19, 1980 would  
4 not have been able to determine which of the published data were clear  
5 enough to show convincingly whether or not glycosylation is required for  
6 biological activity of human fibroblast interferon.” (Exh. 1080 at ¶ 49).

7 96. Dr. Pitha-Rowe is listed as an author in papers<sup>17</sup> published prior to March  
8 of 1980 indicating that non-glycosylated hFIF might be biologically active.  
9 (Exh. 2175 and Exh. 2106).

10 97. A review article by Stewart<sup>18</sup> published in 1979 stated that “[t]hese data  
11 suggest that carbohydrate-free interferons are equally as active as native  
12 glycosylated interferons.” (Exh. 1102 at 181).

13 98. In *Goeddel v. Weissman*,<sup>19</sup> the Board determined that an “an April ’80 EPO  
14 application [did] not constitute a constructive reduction to practice of; the  
15 count” because of a lack of enablement for microbially producing mature  
16 human leuckocyte interferon. (Exh. 1137 at 13).

17 99. It does not appear that all the publications before us, including those  
18 publications describing the Ptashne lab methods, were considered by the  
19 Board in coming to the determination of a lack of enablement.

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<sup>17</sup> Raj et al., *Proc. Natl. Acad. Sci. USA*, 74(4):1483-1487 (1977) (Exh. 2175) and Reynolds et al., *Proc. Natl. Acad. Sci. USA*, 72(12):4881-4885 (1975) (Exh. 2106).

<sup>18</sup> Stewart, *The Interferon System*: 134-183 (1979) (Exh. 1102).

<sup>19</sup> *Goeddel v. Weissmann*, Interference No. 101,601 (BPAI 1995) (final decision) (Ex. 1137), corrected by *Goeddel v. Weissmann*, Interference No. 101,601 (BPAI 1996) (correction on reconsideration) (Ex. 1138).

1     **IV. Discussion**

2             **A.     Substitute Count 2 for Count 1**

3             In each interference Goeddel moves to substitute proposed Count 2 for  
4     Count 1. Both parties agree that the Count of each interference should be limited  
5     to the DNA coding for ('334), or the polypeptide having ('337), the 166 amino  
6     acids of the mature form of hFIF. (FF<sup>20</sup> 28). However, Goeddel takes the  
7     position that the current Count in each interference includes more than the DNA  
8     coding for, or the polypeptide having, the 166 amino acids of the mature form of  
9     hFIF. Goeddel contends that the current Count of each interference includes  
10    within its scope the DNA encoding ('334) or the polypeptide having ('337), the 187  
11    amino acids of the precursor form of hFIF. ('334, Paper 27 at 2 and '337,  
12    Paper 39 at 2).

13   **105,334**

14            The parties agree that the subject matter of the interference should be  
15    limited to DNA coding for only the 166 amino acids of the mature form of hFIF.  
16    (FF 28). Sugano agrees that, "if [the Board finds] that the claims [of Count 1] read  
17    on the precursor [and not just mature hFIF], the Count proposed by Goeddel  
18    would be appropriate...". (Transcript at 32:1-2).

19            Count 1 in interference 105,334 includes claim 6 of the '859 patent.

20            Claim 6 of the '859 patent is as follows:

21            A DNA consisting essentially of a DNA which codes for mature  
22            human fibroblast interferon polypeptide having the amino acid  
23            sequence:  
24

---

<sup>20</sup>     Finding of fact.

1 [166 amino acids of the mature form of hFIF].

2  
3 (FF 8 and 10).

4  
5 We construe claim 6 as requiring DNA that codes for the 166 amino acids  
6 of the mature form of hFIF and as including DNA that codes for the 166 amino  
7 acids plus others. We note, in the context of claim 6, the use of “consisting  
8 essentially of” allows for additional DNA that does not “materially affect [its] basic  
9 and novel characteristic(s)” *In re Herz*, 537 F.2d 549, 551-552 (CCPA 1976).  
10 Goeddel argues that the open language of claim 6 encompasses the precursor  
11 form of hFIF. (‘334, Paper 27 at 9-10). Sugano has not explained why additional  
12 DNA, such as the additional DNA that would allow for DNA coding for the amino  
13 acid sequence of the mature form of hFIF is excluded. In particular, Sugano, in  
14 its opposition, does not provide a satisfactory explanation or evidence  
15 establishing that additional DNA would materially affect the basic and novel  
16 characteristics of the invention.

17 Sugano agrees that if we determine that Count 1 is improper, then Count  
18 2 is an appropriate Count.

19 Proposed Count 2 is as follows:

20 A DNA encoding a mature human fibroblast interferon having a  
21 total of 166 amino acids of the sequence:

22  
23 [listing of the 166 amino acids of mature human fibroblast  
24 interferon]

25  
26 and unaccompanied by a human fibroblast interferon presequence.

27  
28 (FF 32).

29

1           We construe Count 2 as limited to that DNA that encodes for only the 166  
2 amino acids of the mature form of hFIF and not including that DNA that also  
3 would encode for the additional 21 amino acids of the hFIF presequence. We  
4 note that Count 2 is not open to hFIF “having a total of” more than 166 amino  
5 acids given the context of the claim. In particular, since Count 2 indicates “a  
6 total” of the 166 amino acids listed, DNA encoding additional amino acids is  
7 excluded.

8           We GRANT Goeddel Motion 1 in interference 105,334.

9           Goeddel provides persuasive reasons why, and Sugano does not  
10 disagree that, the same claims that were designated as corresponding to Count 1  
11 should be designated as corresponding to Count 2. The interference will be  
12 redeclared to substitute Count 2 for Count 1 and the same claims that were, in  
13 the Declaration (Paper 1), designated as corresponding to Count 1 will also be  
14 designated as corresponding to Count 2.

15          Goeddel noted that Sugano did not move, contingent on the grant of  
16 Goeddel motion 1, for benefit of the ‘931 JP application. Nonetheless, we will  
17 consider the Sugano motion for benefit as to Count 1 as a motion for benefit as  
18 to Count 2 since, in that motion, Sugano addressed the issue of whether the ‘931  
19 JP application is a constructive reduction to practice for what we have  
20 determined to be the scope of Count 2. Moreover, Goeddel opposed the Sugano  
21 motion for benefit as though Count 1 was limited to a DNA encoding mature hFIF  
22 having a total of 166 amino acids and unaccompanied by its presequence.  
23 (‘334, Paper 55 at 9).

The parties agree that the subject matter of the interference should be limited to mature hFIF. (FF 28). Sugano agrees that, “if [the Board] find[s] that the claims [of Count 1] read on the precursor, the Count proposed by Goeddel would be appropriate...”. (Transcript at 32:1-2).

Count 1 in interference 105,334 includes claim 31 the ‘757 Sugano application. (FF 22).

Claim 31 of the ‘757 application is as follows:

Recombinant human fibroblast  $\beta$ 1 interferon having the amino acid sequence:

[listing of the 166 amino acids of mature human fibroblast interferon].

(FF 23).

We construe claim 31 as requiring the 166 amino acids of the mature form of hFIF and as including the 166 amino acids plus others. Goeddel argues that the open language of claim 31 encompasses for the precursor form of hFIF. (‘337, Paper 39 at 7-8). We do not construe the term “having” as precluding the presence of additional amino acids. See *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573 (Fed. Cir. 1997) (In the claim, “[a] DNA transfer vector comprising an inserted cDNA having a [DNA] sequence coding for human [PI]....”, the “word ‘having’ still permitted inclusion of other moieties’.). Moreover, it is not apparent to us, nor has Sugano pointed out in its opposition, why the underlying specification would necessitate a closed construction. See *Lampi Corp. v. American Power Products, Inc.* 228 F.3d 1365, 1376 (Fed. Cir. 2000).

1 In interference 105,337, Goeddel proposed substitute Count 2 is:

2 Claim 49 of Sugano, 08/463,757

3 or

4 Claim 2 of Goeddel, 5,460,811.

5 (FF 33).

6 Proposed Count 2 differs from Count 1 in that involved Sugano claim 49 is  
7 substituted for involved Sugano claim 31. Claim 49 of Sugano 08/463,757 is as  
8 follows:

9 A composition comprising water and a nonglycosylated  
10 mature human fibroblast interferon polypeptide having a total of 166  
11 amino acids and the following amino acid sequence

12  
13 [listing of the 166 amino acids of mature human fibroblast  
14 interferon]

15  
16 ...said composition being free of any glycosylated human fibroblast  
17 interferon.

18  
19 (FF 35).

20 Goeddel claim 2 is similarly limited to claim a composition comprising  
21 water and a nonglycosylated polypeptide having a “total” of the 166 amino acids  
22 of the mature form of hFIF. (FF 24).

23 Thus, we construe the “nonglycosylated polypeptide” of proposed Count 2  
24 as limited to the 166 amino acids of the mature form of hFIF. We note that  
25 Count 2 is not open to hFIF “having” more than 166 amino acids given the  
26 context of the claim. In particular, since Count 2 indicates “a total” of the 166  
27 amino acids listed, DNA encoding additional amino acids is excluded.

28 We GRANT Goeddel Motion 1 in interference 105,337.



1           Goeddel provides persuasive reasons why the same claims, but for  
2   Sugano claim 50, that were designated as corresponding to Count 1 should be  
3   designated as corresponding to Count 2. Sugano does not oppose the claim  
4   designations proposed by Goeddel. In its opposition, Sugano states that it  
5   “recognizes that claim 50, as presently pending, is incorrect and requires  
6   amendment [since] [t]he deposited plasmid is not an expression plasmid and  
7   therefore cannot produce recoverable amounts of recombinant human fibroblast  
8   interferon.” (‘337, Paper 63 at 3; FF 43). We take this as an admission by  
9   Sugano that claim 50 is not patentable. A judgment that Sugano claim 50 is  
10   unpatentable will be entered in a separate paper.

11           The interference will be redeclared to substitute Count 2 for Count 1 and  
12   the same claims that were designated as corresponding to Count 1, but for  
13   Sugano claim 50, will also be designated as corresponding to Count 2.

14           Goeddel notes that Sugano did not move, contingent on the grant of  
15   Goeddel motion 1, for benefit of the ‘931 JP application. We will consider the  
16   Sugano motion for benefit as to Count 1 as a motion for benefit as to Count 2  
17   since, in that motion, Sugano addresses the issue of whether the ‘931 JP  
18   application is a constructive reduction to practice for what we have determined to  
19   be the scope of Count 2. Moreover, Goeddel opposed the Sugano motion for  
20   benefit as though Count 1 was limited to mature hFIF having a total of 166 amino  
21   acids and unaccompanied by its presequence. (‘337, Paper 61 at 8-9).

1           B.       Written Description and Enablement

2           Goeddel moves for judgment that the involved claims in each interference  
3           are unpatentable for lack of written description and lack of enablement.

4           To satisfy the written description requirement, a patent specification must  
5           describe the claimed invention in sufficient detail that one skilled in the art can  
6           reasonably conclude that the inventor had possession of the claimed invention.  
7           *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). “Although  
8           [the applicant] does not have to describe exactly the subject matter claimed ...  
9           the description must clearly allow persons of ordinary skill in the art to recognize  
10          that [the applicant] invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012,  
11          (Fed.Cir.1989) (citations omitted). When determining whether an inventor has  
12          provided adequate written description, either explicitly or inherently, we consider  
13          the disclosure as a whole. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.  
14          Cir. 2000).

15          The enablement requirement of 35 U.S.C. § 112, ¶1, is separate and  
16          distinct from the written description requirement. *Vas-Cath*, 935 F.2d at 1567.  
17          The state of the art existing at the filing date of the application is used to  
18          determine whether a particular disclosure is enabling as of the filing date. *Chiron*  
19          *Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). The sufficiency  
20          of an application’s disclosure under 35 USC §112, ¶1 must be judged as of the  
21          filing date of the application and not the filing date of any ancestor applications.  
22          *Reiffin* at 1346.

1            “It is the specification, not the knowledge of one skilled in the art, that must  
2       supply the novel aspect of an invention in order to constitute adequate  
3       enablement.” *Genentech Inv. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.  
4       Cir. 1997). However, the specification need not disclose what is well-known to  
5       those skilled in the art and preferably omits that which is well-known to those  
6       skilled and already available to the public. *Hybritech, Inc. v. Monoclonal*  
7       *Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

8            We consider whether an undue amount of experimentation would have  
9       been required to practice the claimed invention in determining whether an  
10      enabling disclosure has been provided. The test for whether undue  
11      experimentation would have been required

12           is not merely quantative since a considerable amount of experimentation  
13           is permissible, if it is merely routine, or if the specification in question  
14           provides a reasonable amount of guidance with respect to the direction in  
15           which the experimentation should proceed to enable the determination of  
16           how to practice a desired embodiment of the invention claimed.

17  
18       *Ex parte Jackson*, 217 USPQ 804, 807 (BPAI 1982), cited with approval in *PPG*  
19       *Indus. Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

20           The moving party bears the burden of proof to establish that it is entitled to  
21       the requested relief. Bd. R. 121(b). Thus, Goeddel has the burden of showing  
22       that the Sugano claims lack written description or enablement.

23           Goeddel correctly notes that amino acid sequence and encoding DNA of  
24       hFIF is not explicitly disclosed in the Sugano specifications.. (e.g., ‘337,  
25       Paper 44 at 9). However, Goeddel concedes that one skilled in the art, given the  
26       sequence of Table 5 and the amino acid sequence of Knight, “should have been

1 able to envision a DNA encoding mature hFIF having a total of 166 amino acids  
2 and unaccompanied by the hFIF presequence.” (FF 44). We agree given that:

3 (1) Table 5 discloses the entire precursor sequence which includes  
4 within it the mature sequence (FFs 37- 38),

5 (2) Knight is discussed in the Sugano specifications as disclosing the  
6 first 13 amino acids of mature hFIF (FF 40), and

7 (3) Table 5 shows the end point of mature hFIF (FF 38)  
8 the amino acid, and DNA sequence encoding, of mature hFIF would be  
9 readily apparent.

10 Nonetheless, Goeddel argues that Sugano did not provide any description  
11 of a method for expressing the hFIF gene in a microorganism. According to  
12 Goeddel, “[i]n view of the unpredictable nature of the then-nascent field of  
13 genetic engineering and heterologous expression of proteins”, Sugano must  
14 have described a method for expressing the hFIF DNA in order to have  
15 possession of the claimed subject matter (‘337, Paper 44 at 16-18). Sugano  
16 concedes that the plasmids it discloses would not function to express mature  
17 hFIF (FF 43). Sugano nonetheless asserts that one skilled in the art would have  
18 been able to practice the claimed invention without resorting to undue  
19 experimentation given the state of the prior art.

20 At the outset we note that Sugano’s involved ‘567 patent was filed 6  
21 March 1995 and Sugano’s involved ‘859 patent was filed 27 October 1980. (FF  
22 2). Sugano’s involved ‘757 application was filed 5 June 1995. (FF 16). Thus the  
23 relevant date for assessing whether the Sugano claims lack an enabling

1 disclosure as to the '567 patent and the '757 application is no earlier than 6  
2 March 1995. See *Chiron* at 1254. *Reiffin* at 246. We have not been directed to  
3 evidence showing that the field of the heterologous expression of proteins was  
4 “nascent” or “unpredictable” in March of 1995. There appears to be no dispute  
5 that at least one method for expressing, in *E. coli*, the mature human fibroblast  
6 interferon having a total of 166 amino acids and unaccompanied by its  
7 presequence was known and published in the art as of  
8 27 October 1980. (FF 46). Moreover as Goeddel acknowledges, methods of  
9 expressing mature hFIF in *E. coli* have been published after October of 1980 but  
10 prior to July of 1994. (FF 48).

11 Thus, we do not fully understand Goeddel’s argument that one skilled in  
12 the art would have been unable to practice the claimed invention given the  
13 Sugano specifications. First of all, the relevant date for evaluating each of the  
14 Sugano specifications is its filing date, the earliest of which is in October of 1980.  
15 The record establishes that at least one method of expressing hFIF had been  
16 known in the art for over fourteen years by the time the '757 application and the  
17 application underlying the '567 patent were filed . (FF 46). Secondly, when we  
18 look to Sugano’s earliest accorded benefit date of 27 October 1980 (and the filing  
19 date of the application underlying the '859 patent), we note that the parties agree  
20 that a method for expressing hFIF was known and had published at that time.  
21 (FFs 46-47).<sup>21</sup>

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<sup>21</sup> Goeddel states that its enablement motions address “enablement as of October 27, 1980 since that is the earliest date accorded Sugano in the

1           Goeddel argues that “the art cannot be a *substitute* for a *basic enabling*  
2   *disclosure*, i.e., a specification that is *devoid* of any disclosure of a method of  
3   making the claimed subject matter cannot rely on the art for enablement of its  
4   claims.” (‘337, Paper 43 at 15, original emphasis). In other words, even though  
5   Goeddel concedes that a method for expressing mature hFIF in *E. coli* was  
6   known in the art at the time of filing, we understand it to be Goeddel’s position  
7   that the Sugano specifications did not provide sufficient direction to these  
8   methods . However, given that at least one method for expressing mature hFIF  
9   was known and published in the art at the time each of the Sugano applications  
10   was filed (FFs 46-48), we are not convinced that a detailed description of a  
11   method of expression was necessary to show possession of the claimed  
12   invention. Nor are we convinced that practicing the claimed invention would  
13   have required undue experimentation. In the circumstances before us, Sugano  
14   need not have included a detailed method for expression to provide enablement  
15   since that methods were already available to the public. See *Hybritech* at 1384.

16           Goeddel directs us to *Genentech*, 108 F.3d at 1366 and *Automotive*  
17   *Technologies v. BMW*, 501 F.3d 1274 (Fed. Cir. 2007) in support of its position  
18   that, given the state of the art, Sugano must have expressly described a method  
19   of expression in order to have provided enablement.

20           We do not find *Genentech* and *Automotive Technologies* to support  
21   Goeddel’s position given the record before us. In *Genentech* the specification  
22   described an invention that avoided the difficulties of cleavage by providing

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Declaration.” (See, e.g., ‘334, Paper 32 at 7, fn. 2) However, Goeddel did not file  
a motion attacking the benefit date accorded to Goeddel in either interference.

1 human growth hormone (hgh) unaccompanied by any other extraneous proteins.  
2 When Genentech claimed a method requiring the steps of expressing a DNA  
3 encoding for hgh conjugate protein and then cleaving the conjugate protein by  
4 enzymatic action, the Court determined that Genentech was “attempting to  
5 bootstrap a vague statement of a problem into an enabling disclosure sufficient to  
6 dominate someone else’s solution of the problem.” In Genentech the method  
7 comprising the cleavage step was the novel aspect of the claimed invention yet  
8 the Court found that “[the] specification is so lacking with respect to the limitation  
9 [to enzymatic cleavage] that providing testimony regarding the skill in the art has  
10 been an exercise in futility.” The Court further determined that practicing the  
11 invention would require undue experimentation. *Genentech*, 108 F.3d at 1367).

12 In *Automotive Technologies*, the claims required a “responsive means”  
13 which included an “electronic sensor” but the inventor, “admitted that the  
14 specification fails to disclose structure for any of the technologies mentioned [for  
15 electronic sensing].” *Id.* at 1283. Moreover, expert testimony and the inventor’s  
16 own testimony indicated that functional electronic sensors were not known in the  
17 art at the relevant time.

18 Unlike in *Genentech* and *Automotive Technologies*, the Sugano  
19 specifications provide sufficient detail of what the claimed invention is, i.e.,  
20 mature hFIF polypeptides or DNA encoding the polypeptide by providing the  
21 nucleotide and amino acid structures and direction that the polypeptide could be  
22 expressed in *E. coli*. While the involved Sugano specifications themselves did  
23 not disclose details of a method of expressing the hFIF in *E. coli* (including a step

1 of provided the DNA molecule encoding mature hFIF), at least one method of  
2 expressing hFIF in *E. coli* was well known in the art and published by the time the  
3 involved applications were filed. (FF 47). Furthermore, we do not determine that  
4 the involved technology was “unpredictable” or in its “early stages of  
5 development” at the time the involved applications were filed such that undue  
6 experimentation would have been required to make the claimed invention.  
7 While we agree that a specification may not describe a claimed invention if it  
8 merely provides a “germ of an idea” of the claimed subject matter, the Sugano  
9 specifications do not fall into that category. *Cf. Genentech*, 108 F.3d at 1366-  
10 1368.

11       Goeddel argues that the September 1980 Goeddel publication was the  
12 result of the work of one “extraordinarily skilled in the art.” (e.g., ‘337, Paper 43 at  
13 15). We are not persuaded by this argument since: (1) the publication itself  
14 reported a method for expressing mature hFIF in *E. coli* and thus, after  
15 publication, became part of the knowledge of one of ordinary skill in the art and  
16 (2) at the time the ‘757 application and the application underlying the ‘567 patent  
17 were filed, additional publications reported a method for expression of hFIF in  
18 *E. coli*. (FF 48).

19       In interference 105,334, Goeddel motions 6 and 7 are DENIED.

20       In interference 105,337, Goeddel motions 5 and 6 are DENIED.

21       C. Benefit

22       Sugano moves for benefit of its ‘931 JP application as to Count 1. We  
23 grant Goeddel’s motion to substitute Count 2 in each of interferences 105,334



1 and 105,337. Sugano did not move, contingent on the grant of the Goeddel  
2 motion to substitute a count, for benefit of the JP application as to Count 2.  
3 Nonetheless, we consider Sugano's benefit motion as a motion for benefit as to  
4 Count 2 since the motion (as well as Goeddel's opposition) address whether the  
5 JP application provided a constructive reduction to practice within the scope of  
6 Count 2.

7 In order to be entitled to benefit for the purpose of priority for an earlier  
8 filed application that application must contain a described and enabled  
9 anticipation under 35 U.S.C. §102(g)(1) that has been continuously disclosed  
10 through a chain of patent applications including the involved application or  
11 patent. For the chain to be continuous, each subsequent application must have  
12 been copending under 35 U.S.C. §120 or §121 or timely filed under 35 U.S.C.  
13 §119 or §365(a). Bd. R. 201.

14 In addition, a party seeking priority benefit of an earlier filed application  
15 must provide a copy of the application along with a certified translation of a non-  
16 English application. Standing Order at ¶ 208.4.1, Bd. R. 154(b).

17 As the moving party, Sugano has the burden of establishing that it is  
18 entitled to the requested relief. Bd. R. 121(b).

19 Sugano seeks priority benefit of the '931 JP application filed 19 March  
20 1980. It is not disputed that the chain of applications leading back to the JP  
21 application were timely filed. Sugano has supplied a copy of the JP application  
22 as well as a certified translation of the application. (FF 52).

1           The issue before us is whether the '931 JP application provided written  
2   description and enablement for DNA coding for ('334), or the polypeptide having  
3   ('337), a total of the 166 amino acids of the mature form of hFIF.

4           The '931 JP disclosure is quite similar, but is not identical, to the  
5   disclosure in the involved Sugano specifications. (FF 53). However, the '931 JP  
6   application does not indicate by numbering the first amino acid in the Table 5  
7   amino acid sequence and contains the word "Ter" after the last amino acid, i.e.,  
8   "Asn" but otherwise Table 5 of the '931 JP application and Table 5 of the involved  
9   Sugano applications and patents appear to be the same. (FF 54)

10          The '931 JP application does not contain the statement that "the entire  
11   amino acid sequence for hFIF (amino acids 1-166) and its putative signal peptide  
12   (amino acids -21 to -1)" is shown in the DNA sequence at Table 5. (FF 55).

13          Nonetheless, for much the same reasons we noted above in denying the  
14   Goeddel motion for lack of written description support, we find that the '931  
15   application provided sufficient written description and enablement for the DNA  
16   coding for, and the polypeptide having the amino acid sequence of, mature hFIF.  
17   The sequences of mature hFIF DNA or polypeptide are not explicitly disclosed.  
18   As Goeddel concedes, one skilled in the art, given the sequence of Table 5 and  
19   the amino acid sequence of Knight, "should have been able to envision a DNA  
20   encoding mature hFIF having a total of 166 amino acids and unaccompanied by  
21   the hFIF presequence." (FF 44). We agree given that:

22          (1)     Table 5 disclosed the precursor sequence (FFs 53-55),

1           (2) Knight is discussed in the '931 JP application as disclosing the first  
2 13 amino acids of mature hFIF (FFs 41 and 53-55), and

3           (3) Table 5 discloses the end point of hFIF (FFs 53-55)  
4 the amino acid of, and DNA sequence encoding, mature hFIF would be  
5 readily apparent.

6           The '931 JP application itself does not disclose in detail how to express  
7 mature hFIF in *E. coli*, which would include the step of making the DNA molecule  
8 needed to express mature hFIF. Thus, we find that the guidance provided by the  
9 '931 JP application is minimal. However, in evaluating whether sufficient  
10 enablement was provided we look not just to the '931 JP application itself but  
11 also to, *inter alia*, the level of skill in the art and the state of the art at the time of  
12 filing, i.e., 19 March 1980. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)  
13 ("Factors to be considered in determining whether a disclosure would require  
14 undue experimentation ...include ... (2) the amount of direction or guidance  
15 presented... (5) the state of the prior art, (6) the relative skill of those in the  
16 art....).

17           We determine that Sugano has established that methods were known at  
18 the relevant time for directly expressing proteins in *E. coli* and that one skilled in  
19 the art would have been able to express mature hFIF using techniques that were  
20 known in the art. Sugano has also established that one skilled in the art would  
21 have expected that these non-glycosylated proteins would obtain at least some  
22 biological activity. Based on the testimony of Dr. Roberts and the testimony of  
23 Drs. Content and Lauer, and the publications pointed out to us, Sugano has set

1    forth a *prima facie* case showing that it is entitled to benefit of the '931 JP  
2    application.

3            In particular we credit Dr. Robert's testimony that:

4            [T]o make a human fibroblast interferon dDNA without any leader  
5            sequence, the cDNA can be digested with exonuclease III and S1  
6            or other nucleases in order to generate a number of clones, one of  
7            which would have all of its presequence digested up to the mature  
8            ATG sequence. In fact, Goeddel's U.S. Patent 4,342,832 [issued  
9            on 3 August 1982<sup>22</sup>] explicitly teaches that exonuclease III and S1  
10           can be used to remove leader sequences. After digestion, the  
11           clones are religated [sic], transformed into bacteria, and plasmid  
12           DNA can then be purified and analyzed, for example, by acrylamide  
13           gel analysis. Acrylamide gel analysis will allow the practitioner to  
14           determine which clones might have the entire presequence  
15           digested away. These clones can then be sequenced to confirm  
16           which ones only have the coding sequence for mature interferon,  
17           i.e., without coding sequence for the presequence. Alternatively,  
18           protein extracts from bacterial clones can be tested by  
19           immunoassays to identify potential clones that express the protein.  
20           Plasmids from these potential clones can be purified and  
21           sequenced to confirm which plasmids contain only the coding  
22           sequence for the mature interferon. Although this process can be  
23           labor intensive, the necessary methods....were well established in  
24           the art at least as of March 19,1980.

25  
26            (FF 71).

27            To the extent that Dr. Robert's testimony conflicts with the testimony of Dr.  
28    Dernyck on whether one skilled in the art could have made mature hFIF in view  
29    of the guidance provided in the '931 JP application and techniques known in the  
30    art, in particular the Ptashne lab methods, we credit Dr. Robert's testimony as  
31    well as the testimony of Drs. Content and Lauer (FF 79) over that of Dr. Dernyck.

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<sup>22</sup>        Because the Goeddel patent issued after 19 March 1980, we do not consider it as part of the knowledge of one skilled in the art at the time of the filing of the '931 JP application.

1 First, we note that Dr. Dernyck agrees that, given the sequence of  
2 precursor hFIF and the disclosure of Knight (both found in the '931 JP  
3 application), one skilled in the art should have been able to envision the  
4 sequence of mature hFIF. (FF 84).

5 Secondly, we note the Dr. Dernyck agrees that the Ptashne lab methods  
6 would have allowed for production of clones that would express mature hFIF.  
7 (FF 86). While Dr. Dernyck testified that there would be a large amount of  
8 screening necessary to identify the appropriate clones and that the necessary  
9 screening would have been "unduly burdensome," (FF 86) we are not convinced  
10 that the screening required would amount to undue experimentation. See *Wands*,  
11 858 F.2d at 737, (citing *In re Jackson*, 217 USPQ 804, 807 (BPAI 1982). "The  
12 test is not merely quantitative, since a considerable amount of experimentation is  
13 permissible, if it is merely routine, or if the specification in question provides a  
14 reasonable amount of guidance with respect to the direction in which the  
15 experimentation should proceed."). Even if the desired clones were only found at  
16 a frequency of .01% (FF 87), it does not follow that the amount of  
17 experimentation needed to screen for the clones was undue. Dr. Rogers testified  
18 that there were multiple known methods of screening that would result in  
19 identification of clones useful for the expression of mature hFIF with only routine  
20 experimentation. (FFs 71 -74). Moreover, while, as noted by Goeddel, it  
21 appears that a better method for screening was developed after  
22 19 March 1980, it does not follow that the former procedure would not have  
23 worked sufficiently. (FF 88). We are not convinced, based on the record before

1 us, that the screening procedures required undue experimentation. To the extent  
2 that Drs. Derynck and Roberts have provided conflicting testimony on the amount  
3 of experimentation that would have been required, we credit Dr. Roberts'  
4 testimony.

5 We also note that Dr. Derynck had provided a sworn statement in another  
6 proceeding indicating that only methods known in the art as of March of 1980  
7 were used to express hFIF. (FF 89). Dr. Derynck, on cross-examination in the  
8 interferences, disputes that he was speaking only of mature hFIF or methods  
9 available to the public in the sworn statement. (FF 89). The lack of a clear and  
10 consistent position by Dr. Derynck is an additional reason that we do not credit  
11 Dr. Derynck's testimony over Dr. Roberts' testimony.

12 We also have considered Goeddel's argument that in *Goeddel v.*  
13 *Weissman*, the Board determined that a 1980 EPO application did not amount to  
14 a constructive reduction to practice because of a lack of enablement for  
15 microbially produced mature human leukocyte interferon. (FF 98). We are not  
16 persuaded that we should adopt the Board's position in *Weissmann*. For  
17 example, the record before us is different than in *Weissmann*. We note that it  
18 does not appear that the Ptashne lab methods were considered by the Board in  
19 *Weissmann*. (FF 99).

20 Dr. Roberts pointed to papers published prior to March of 1980 reporting  
21 that non-glycosylated interferons expressed in bacteria would be expected to be  
22 active. (FF 75). Dr. Roberts testified that one skilled in the art, having reviewed

1 the published art as of March of 1980, would have found it likely that completely  
2 non-glycosylated human interferons would maintain activity. (FF 76).<sup>23</sup>

3 Dr. Robert's testimony is consistent with the Stewart review article  
4 published in 1979 where it is noted that previously published data suggests that  
5 "carbohydrate-free interferons are equally as active as native glycosylated  
6 interferons." (FF 97).

7 Dr. Pitha-Rowe testified that, despite reports in the art that non-  
8 glycosylated interferons would be expected to be active, "researchers as of March  
9 19, 1980 would not have been able to determine which of the published data were  
10 clear enough to show convincingly whether or not glycosylation is required for  
11 biological activity of human fibroblast interferon." (FF 95).

12 We have considered Dr. Pitha-Rowe's criticisms of the particular papers  
13 reporting activity for non-glycosylated interferons. However, when we consider  
14 the papers published as of March 1980 (including those by Dr. Pitha-Rowe (FF  
15 96)) as a whole we determine that Sugano has shown that one skilled in the art  
16 would have had a reasonable expectation that non-glycosylated interferons  
17 would have at least some biological activity. To the extent Drs. Roberts' and  
18 Pitha-Rowe's testimony conflict as to whether one skilled in the art would have  
19 expected hFIF expressed in *E. coli* to have activity, we credit Dr. Roberts'  
20 testimony. Dr. Roberts' testimony is supported by a number of contemporaneous

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<sup>23</sup> On cross-examination, Dr. Roberts stated that he did not consider himself to be an expert in the glycosylation of proteins. (Exh. 1134 at 8:17-9:10). Given Dr. Roberts' background and the published papers he has considered, we find him qualified to provide the opinion of one having ordinary skill in the art as of March 1980.

1 publications, including the review article by Stewart. On the other hand, Dr.  
2 Pitha-Rowe's testimony, while perhaps raising some questions about some of the  
3 data reported in the publications discussed by Dr. Roberts in his testimony, does  
4 not overcome what the evidence shows to have been an acceptance in the art  
5 that non-glycosylated interferons would have been expected to have at least  
6 some form of biological activity.

7 Sugano has met its burden of showing that its '931 JP application  
8 described and enabled embodiment within the scope of the Count 2 in each  
9 interference. Thus, in each interference, we GRANT Sugano motion 4.

10 D. Patentability Motions

11 In each interference, we grant Sugano's motion for benefit of the '931 JP  
12 application. In each interference, Goeddel's earliest alleged date of conception is  
13 later than the filing date of the '931 JP application. Accordingly, Goeddel cannot  
14 prevail on priority.

15 Goeddel has filed a number of motions alleging that some of the involved  
16 Sugano claims are unpatentable over prior art ('334 at Papers 29-31 and '337 at  
17 Papers 41 and 42),<sup>24</sup> the natural human chromosome ('334 at Paper 28 and '337  
18 at Paper 40) and or for lack of utility ('334 at Paper 34 and '337 at Paper 40). We  
19 need not decide those motions to complete our determination of priority. We  
20 note that:

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<sup>24</sup> In 105,334, Goeddel motions 4 and 5 were deferred and in 105,337  
Goeddel motion 3 and 4 were deferred ('334 at Paper 54 and '337 at Paper 60).  
These motions were filed but no oppositions or replies were filed.



1           (1)     neither any motion individually, nor the combination of the motions,  
2     attack the patentability of all of the involved Sugano claims in either interference.  
3     Thus, even if we granted each Goeddel motion attacking patentability, Sugano  
4     would have claims directed to mature hFIF and encoding DNA remaining in the  
5     interference,

6           (2)     a decision on the patentability of the attacked Sugano claims is not  
7     necessary to a determination of priority,

8           (3)     the Sugano claims that Goeddel contends are unpatentable are not  
9     part of the substitute Count of either interference and thus deciding the  
10    patentability motions could not have the effect of changing the Count,

11          (4)     in interference 105,334, at least as to the prior art challenges,  
12    Goeddel has an alternative remedy under 35 USC § 302, and

13          (5)     in interference 105,337, the Board will recommend that the  
14    Examiner, upon the resumption of *ex parte* prosecution, consider the motions  
15    filed by Goeddel that attack the patentability of the Sugano claims (as well as any  
16    Sugano oppositions and Goeddel replies). Bd.R. 127(c).

17           In each interference, Sugano motions 1 through 3 have been deferred.  
18    ('334 at Paper 47 and 54 and 337 at Papers 51 and 60). Since judgment will be  
19    entered against Goeddel in each interference, we need not and do not decide  
20    these deferred motions.

21           E.     Miscellaneous Motions

22           In each interference, Goeddel moves to exclude the following exhibits:  
23    2017, 2165, 2167, and 2171. ('334 at Paper 82 and '337 at Paper 85). Because

1 we did not rely upon these exhibits as a basis for our decision, we need not and  
2 do not decide the Goeddel motion to exclude.

3 In each interference, Sugano moves to exclude Goeddel exhibits 1150-  
4 1170, 1172-1178, 1180, and 1181 and the Goeddel replies that rely upon the  
5 exhibits (i.e., Goeddel Replies 1, 7, and 8 in 105,334 and Goeddel Replies 1 and  
6 7 in 105,337). ('334 at Paper 86 and '337 at Paper 89 ). Because we did not rely  
7 upon these exhibits as a basis for our decision, we need not and do not decide  
8 the Sugano motion to exclude.

## 9 **V. Summary**

10 In each interference:

11 (1) we grant the Goeddel motion to substitute Count 2 for Count 1,

12 (2) we deny the Goeddel motions for judgment based on a lack of  
13 written description or enablement,

14 (3) we dismiss all other Goeddel motions, and

15 (4) we grant Sugano's motion for benefit of the '931 JP application.

16 We dismiss all other Sugano motions. Because Goeddel has not alleged a date  
17 that is prior to Sugano's earliest accorded benefit date, Goeddel cannot prevail in  
18 the interference.

19 The interference will be redeclared with Count 2 and Sugano designated  
20 as senior party.<sup>25</sup> Judgment on priority will be entered against Goeddel in each  
21 interference. Bd. R. 127(a).

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<sup>25</sup> The parties will not be given an opportunity to provide updated priority statements as to Count 2 since Count 2 is narrower in scope than Count 1.

1     **VI.     ORDER**

2             Upon consideration of the record, it is

3                     ORDERED that in interference 105,334:

4                             Goeddel Motion 1 is GRANTED;

5                             Goeddel Motions 2 through 5 and 8 are DISMISSED;

6                             Goeddel Motions 6 and 7 are DENIED;

7                             The Goeddel miscellaneous motion to exclude evidence is  
8 dismissed;

9                             Sugano Motion 1-3 are DISMISSED;

10                            Sugano Motion 4 is GRANTED;

11                            The Sugano miscellaneous motion to exclude evidence is  
12 dismissed;

13                            FURTHER ORDERED that in interference 105,337:

14                            Goeddel Motion 1 is GRANTED;

15                            Goeddel Motions 2 through 4 and 7 are DISMISSED;

16                            Goeddel motions 5 and 6 are DENIED;

17                            The Goeddel miscellaneous motion to exclude evidence is  
18 dismissed;

19                            Sugano Motions 1-3 are DISMISSED;

20                            Sugano Motion 4 is GRANTED;

21                            The Sugano miscellaneous motion to exclude evidence is  
22 dismissed.

23

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**United States Court of Appeals  
For the Federal Circuit**

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DAVID V. GOEDDEL AND ROBERTO CREA,

*Appellants,*

v.

HARUO SUGANO, MASAMI MURAMATSU,  
AND TADATSUGU TANIGUCHI,

*Appellees.*

U.S. COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

APR 15 2009

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**Appeals From The United States Patent and Trademark Office,  
Board of Patent Appeals and Interferences**

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**BRIEF OF APPELLANTS GOEDDEL**

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## CERTIFICATE OF INTEREST

Counsel for the appellants certifies the following:

1. The full name of every party or amicus represented by me is:  
David V. Goeddel and Roberto Crea
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:  
Genentech, Inc.  
Hoffmann-La Roche Inc.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:  
Roche Holdings, Inc. (Delaware) has a controlling interest in Hoffmann-La Roche Inc. and Genentech, Inc.

While counsel is not aware that they have any direct ownership of stock in the parties he represents (Hoffmann-La Roche Inc. and Genentech, Inc.), Roche Holding AG of Switzerland has a controlling interest in Roche Holdings, Inc. (Delaware) and Novartis AG of Switzerland is reported to own more than 10% of the voting stock of Roche Holding AG.

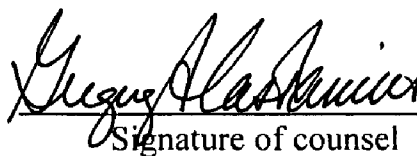
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Jones Day: Thomas E. Friebe; Jennifer J. Chheda; Michael J. Ryan; and Gregory A. Castanias

Gibbons P.C.: George M. Gould, William H. Epstein and David E. De Lorenzi.

April 15, 2009

Date

  
Signature of counsel

Gregory A. Castanias

Printed name of counsel

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## ABBREVIATIONS APPEARING IN THIS BRIEF

### Parties:

Goeddel	Appellants David V. Goeddel and Roberto Crea
Sugano	Appellees Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi

### Defined Terms:

'567 patent	U.S. Patent No. 5,514,567
'757 application	U.S. Application No. 08/463,757
'811 patent	U.S. Patent No. 5,460,811
'859 patent	U.S. Patent No. 5,326,859
A _____	Joint Appendix page
Board	Board of Patent Appeals and Interferences of the United States Patent and Trademark Office
bp	Base pair
DNA Interference	Interference No. 105,334
hFIF	Human fibroblast interferon
hGH	Human growth hormone
Japan application	Japan application No. 33931/1980
Knight	Knight, "Human Fibroblast Interferon: Amino Acid Sequence Analysis and Amino Terminal Amino Acid Sequence," <i>Science</i> <u>207</u> : 525-26 (February 1980)
Protein Interference	Interference No. 105,337
Section 102(b)	35 U.S.C. § 102(b)

Section 112	35 U.S.C. § 112
Section 135(b)	35 U.S.C. § 135(b)
U.S.	United States

### **STATEMENT OF RELATED CASES**

Counsel for Goeddel is unaware of (1) any other appeal in or from the Board of Patent Appeals and Interferences in these interferences, or (2) any case pending before this Court, or another court, that may affect or be affected by this Court's decision in the present appeal.

## STATEMENT OF JURISDICTION

The jurisdiction of this Court is based upon 28 U.S.C. §§1295(a)(4)(A) and 35 U.S.C. §§141 and 142. This is a consolidated appeal from the final judgments of the Patent and Trademark Office's Board of Patent Appeals and Interferences ("Board"), dated September 29, 2008, in two patent interferences conducted pursuant to 35 U.S.C. §135(a). Goeddel timely filed notices of its appeals on December 1, 2008.

## STATEMENT OF THE ISSUES

1. Whether the Board erred in concluding that appellees' Japan application, priority benefit of which appellees sought in both interferences, contains a written description of a compound of the count of each interference, since there is no evidence that one skilled in the art would have concluded that *the inventors themselves* described such compounds *in the Japan application*.

2. Whether the Board erred in concluding that the Japan application contained a *written description of a method for making* a compound of the count of each interference, *i.e.*, contained an enabling disclosure, where there is no suggestion to make such compounds or a description of a method for making them, and where the Board relied *entirely* on methods extrinsic to and not referenced in the application to satisfy enablement.



3. Whether the Board abused its discretion in one of the interferences by refusing to decide three authorized and briefed motions attacking patentability of appellees' involved patent claims, where one of those motions alone would, if granted, render all of appellees' involved claims unpatentable.

### INTRODUCTION

This appeal involves two interferences declared to determine which of two inventor groups—David V. Goeddel *et al.* (“Goeddel”) or Haruo Sugano *et al.* (“Sugano”)—is entitled to priority. The inventions at issue are (i) a DNA molecule encoding a therapeutically useful “mature” human fibroblast interferon (“hFIF”) having a total of 166 amino acids and *unaccompanied* by its 21-amino acid presequence and (ii) a therapeutically useful nonglycosylated “mature” hFIF having a total of 165 or 166 amino acids.

There is no dispute that Goeddel constructively reduced the inventions to practice in a September 1980 patent application, which was filed prior to the date initially accorded Sugano for a constructive reduction to practice of each count, rendering Goeddel the senior party in each interference upon declaration. But in its final decision, the Board accorded Sugano priority after awarding it the benefit of a March 1980 Japan application which, in the Board's view, described and enabled the inventions of the counts.

The Board erred as a matter of law because Sugano's Japan application contains no written description of the contested inventions, or methods for making those inventions. The contested inventions are the specific compounds described above. But in its Japan application, Sugano expressly described its inventions as something else, *i.e.*, different compounds, namely, a DNA molecule encoding the 187-amino acid hFIF precursor and a polypeptide having the 187 amino acids of the precursor, which is not therapeutically useful in humans.

Sugano's Japan application nowhere describes or claims a molecule of the DNA count, and it nowhere even hints at, much less describes, the extraordinarily complex procedure—fully described by Goeddel but never described in *any* Sugano application—through which a DNA molecule encoding the precursor could be converted to a DNA molecule encoding mature, therapeutically useful hFIF unaccompanied by its presequence. In fact, Sugano's Japan application never sets forth the desirability of a molecule of the DNA count. The Board, however, erroneously held that the Japan application satisfied the written description requirement because one skilled in the art could purportedly have “envisioned” a mature hFIF unaccompanied by its presequence and a DNA molecule encoding it, though neither was described, claimed or even envisioned in the Japan application itself. That was pure legal error.

For the same reasons, Sugano's Japan application did not describe or claim a polypeptide of the "protein" count. Further, since that Japan application fails to describe how to make a molecule of the DNA count, the application lacks written description of a method for making a compound of the protein count *because such a method requires a molecule of the DNA count.*

Accordingly, for these and other reasons, the judgment of the Board should be reversed.

### **STATEMENT OF THE CASE**

Goeddel and Sugano were involved in two patent interferences before the Board in which junior party Sugano had moved to be accorded benefit of its Japan application for the single count of each interference. Goeddel opposed on grounds that the Japan application (i) lacked a written description of an embodiment of either count and (ii) lacked a written description of a method of making an embodiment of either count, *i.e.*, lacked an enabling disclosure. In the "DNA" interference, Goeddel also moved for a determination that all of Sugano's involved claims are in any event unpatentable.

In a final decision, the Board held that Sugano was entitled to the benefit of its Japan application for the count of each interference and that Sugano had priority

over Goeddel. (A000053).<sup>1</sup> The Board then concluded that it need not decide Goeddel's three motions for unpatentability of Sugano's claims. (A000053-54). Goeddel now appeals the Board's decisions according Sugano benefit of its Japan application in each interference and, in the DNA interference, dismissing Goeddel's three unpatentability motions, as well as the Board's final judgments awarding priority of invention to Sugano.

## **STATEMENT OF THE FACTS**

### **A. The Interfering Subject Matter**

The subject matter of the "DNA" interference (Interference No. 105,334) is a DNA molecule that has been engineered to encode a mature hFIF having a total of 166 amino acids of a recited sequence and unaccompanied by a hFIF presequence. (A000017, FF28; A000018, FF32). The subject of the "protein" interference (Interference No. 105,337) is a nonglycosylated "mature" hFIF polypeptide having a total of 165 or 166 amino acids and unaccompanied by a hFIF presequence in an aqueous composition that is free of any glycosylated hFIF. (A000017, FF28; A000019, FF35). For convenience, the invention of the protein interference is often described solely in terms of the polypeptide required by the count, despite that the count recites an aqueous composition containing that

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<sup>1</sup> Because the opinions in the two interferences are identical, only the decision for Interference No. 105,334 is cited herein.

polypeptide and free of any glycosylated hFIF, because it is the mature hFIF polypeptide that is the focus of the issues here.

Fibroblast interferon, which is naturally produced in the human body, is an important defense against viruses, and in synthetic form has proven useful in combating disease. (A300219-24; A300232-39; A300240-45). The naturally-occurring gene for hFIF codes for the “precursor form” of the protein, which has a total of 187 amino acids. (A300273, ¶13). The first 21 amino acids of the precursor constitute a “presequence,” also known as a “signal peptide” or “leader sequence.” *Id.* The following 166 amino acids, when cleaved from the presequence, constitute mature hFIF. *Id.* In human cells expressing the naturally-occurring gene, the 187-amino acid precursor is initially produced but this precursor is precisely cleaved to remove the 21-amino acid presequence, and it is the 166-amino acid mature hFIF that is secreted from the cell. *Id.* There is no evidence that recombinant bacterial cells are capable of precisely cleaving away the 21-amino acid presequence.

Over Sugano’s opposition, the Board adopted a substitute DNA count proposed by Goeddel (A000035, line 8), which reads as follows:

A DNA encoding a mature human fibroblast interferon having a total of 166 amino acids of the sequence:

[listing of the 166 amino acids of mature hFIF]

and unaccompanied by a human fibroblast interferon presequence. (A000018, FF32). Thus, the substitute count is explicitly limited to DNA molecules encoding a mature hFIF having *a total of 166 amino acids* and *unaccompanied* by a hFIF presequence, which polypeptide is the molecule that is *therapeutically useful in humans*. It does not encompass, *as did the original count that the Board rejected*, DNA molecules encoding additional amino acids, such as are found in the 187-amino acid hFIF precursor, which precursor is not therapeutically useful in humans. (A000035, lines 1-7).

Again over Sugano's opposition, the Board adopted a substitute protein count proposed by Goeddel. (A000037, line 28). The protein count specifically recites a "mature" hFIF polypeptide having a total of 165 or 166 amino acids.<sup>2</sup> (A000018, FF33; A000019, FF35; A000016, FF24). That polypeptide is useful for human therapy. The substitute protein count does not encompass, *as did the original count that the Board rejected*, a nonglycosylated polypeptide having more than 166 amino acids, such as are found in the 187-amino acid hFIF precursor. *Id.* at lines 23-27.

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<sup>2</sup> The 166-amino acid polypeptide has methionine (Met) as its amino-terminal amino acid (X=methionine); the 165-amino acid polypeptide lacks that amino-terminal methionine (X=hydrogen). (A300563, col. 3, lines 57-64).

The DNA molecules of the DNA count are uniquely useful for the direct expression<sup>3</sup> in bacteria of the polypeptides recited in the protein count. Since the 165- and 166-amino acid mature hFIF polypeptides are therapeutically useful in humans, while the 187-amino acid hFIF precursor is not, the DNAs and polypeptides recited in the counts are different inventions as compared to DNAs encoding the hFIF precursor and that 187-amino acid polypeptide. Indeed, it is undisputed that a clinical researcher of ordinary skill in 1980 would have considered the hFIF precursor to be unsuitable for therapeutic use in humans. (A300263, ¶42). This is confirmed by the fact that, while the Food and Drug Administration has approved for therapeutic use in humans a product that is produced in bacteria from a DNA molecule encoding a mature hFIF unaccompanied by a hFIF presequence (A300265, ¶49), it has never approved a hFIF precursor for human therapy (A300264, ¶47).

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<sup>3</sup> “Direct expression” connotes initiation of protein synthesis from the ATG codon coding for the amino-terminal amino acid mature protein rather than the ATG coding for the amino-terminal amino acid of the presequence (signal peptide) of the precursor. (A300109, first sentence of “Direct expression of fibroblast interferon;” A300814, lines 25-27).

**B. Procedural Background Through Declaration Of The Interferences**

**1. Interference No. 105,334—The DNA Interference**

Sugano was issued two patents that are involved in the DNA interference: Patent Nos. 5,326,859 (“’859 patent;” A300481-91), issued July 5, 1994, and 5,514,567 (“’567 patent;” A300492-505), issued May 7, 1996. (A000011, FF2). The interference arises because Goeddel’s application No. 07/374,311, filed June 30, 1989 (A300810-843), claims the same subject matter as certain claims of the Sugano patents.

Upon declaration, Goeddel was accorded benefit for priority purposes of three earlier-filed applications, the earliest of which is U.S. application No. 06/190,799, filed September 25, 1980. (A000014, FF12). With respect to the ’567 patent, Sugano was accorded benefit of two earlier-filed U.S. applications, the earliest of which is application No. 06/201,359, filed October 27, 1980, which issued as Sugano’s second involved patent, the ’859 patent. *Id.*

**2. Interference No. 105,337—The Protein Interference**

Goeddel was issued a patent on the subject matter of the protein interference: Patent No. 5,460,811 (“’811 patent;” A300554-76), issued October 24, 1995. (A000015, FF19). The interference was declared because Sugano’s application No. 08/463,757, filed June 5, 1995 (“’757 application;” A300506-28) claims the same subject matter as certain claims of the Goeddel ’811 patent.



Upon declaration, Goeddel was accorded benefit of the same September 25, 1980 application it was accorded benefit of in the DNA interference. (A000016-17, FF25). Sugano was accorded benefit of the same October 27, 1980 application it was accorded benefit of in the DNA interference. *Id.*

Upon declaration of both interferences, Sugano was *not* accorded benefit of its Japan application No. 33931/1980, filed March 19, 1980 (“Japan application;” A306433-51). (A000014, n.3 and A000017, n.4). Thus, Goeddel was named senior party in both interferences. The principal question in both appeals is whether Sugano was properly found to have overcome Goeddel’s earliest accorded benefit date by showing that its Japan application contains a constructive reduction to practice of the count.

### **C. The Parties’ Motions Relevant To These Appeals**

In each interference, Sugano filed a motion seeking to be accorded benefit of its earlier-filed Japan application for the original count. (A001733-63; A005349-78). Goeddel opposed on grounds that Sugano’s Japan application failed to present a constructive reduction to practice of an embodiment of the count in the manner required by 35 U.S.C. §112, first paragraph. In particular, Sugano’s Japan application lacked (i) a written description of a molecule within each count and (ii) a written description of a method for making, *i.e.*, enablement for, a molecule within each count. (A001879-953; A005724-90). After substituting Goeddel’s

proposed count for the original count in each interference, the Board treated Sugano's motion for benefit for original count 1 as a motion for benefit for substitute count 2. (A000035, lines 16-18; A000038, lines 15-16).

In the DNA interference, Goeddel also filed three motions for judgment that Sugano's involved claims are unpatentable under 35 U.S.C. §101 (over the human chromosome, a product of nature; A001294-335), §§102(b) and 103(a) (over prior art; A001336-89), and §§101 and 112 (for lack of utility; A001551-90). All three motions were authorized (A001174-80; A001184-92) and briefed. (A000008, lines 13-18; A000009, lines 1-3). Goeddel's motion for lack of utility was directed against *all* of Sugano's claims involved in the DNA interference. (A001554, lines 2-5).

**D. Sugano's Japan Application Fails To Describe A 165- Or 166-Amino Acid Mature hFIF Unaccompanied By Its Presequence, Or DNAs Encoding The 166-Amino Acid Mature Polypeptide**

**1. The Japan Application Itself Describes Only The 187-Amino Acid hFIF Precursor, And DNAs Encoding That Precursor**

As set forth in its title, Sugano's Japan application describes preparation of recombinant plasmids having the "human fibroblast interferon messenger RNA gene." (A306435). That human interferon gene encodes the 187-amino acid hFIF precursor, as shown in Table 5 of the application. (A306449). Sugano's Japan application describes the invention as "[n]ovel recombinant plasmids that are made

by inserting a DNA synthesized with human fibroblast interferon messenger RNA as a template into a vector plasmid DNA, having a gene which encompasses *at least the entire coding region* of the human fibroblast interferon messenger RNA” (emphasis added). (A306435, lines 6-10). There is no description in this application of recombinant plasmids encoding the 166-amino acid mature hFIF unaccompanied by its presequence.

Sugano repeated that their invention was the gene that encodes the *entire* coding region of the 187-amino acid precursor hFIF. The first sentence of the “Detailed Description of the Invention” states that “[t]his invention relates to novel recombinant plasmids having the human fibroblast interferon messenger RNA gene,” again referring to DNA molecules encoding the 187-amino acid precursor. *Id.* at lines 14-16. At page 2, Sugano states:

That is, this invention relates to a novel recombinant plasmid, having a gene which encompasses *at least the entire coding region* of the human fibroblast interferon messenger RNA . . . .

. . .

*“The entire coding region” means the part specifying the whole amino acid sequence of the protein of the human fibroblast interferon in the human fibroblast interferon messenger RNA sequence.*

The novel recombinant plasmid (or recombinant plasmid DNA) having a gene which encompasses *the entire coding region* of the human fibroblast interferon messenger RNA has been obtained for the first time by the present inventors.

(A306436, lines 13-32; emphasis added). The inventors again noted that they had isolated a DNA molecule encoding the entire coding region for the 187-amino acid precursor which could be used to mass produce “interferon,” but with no description of the structure of that “interferon”:

The present novel recombinant plasmids having a gene which encompasses *at least the entire coding region* of the human fibroblast interferon mRNA are very useful because they enable mass production of *interferon* in Escherichia coli or in eukaryotic cells which can be grown in a large scale.

(A306441, lines 28-33; italics added).

Sugano commented on why they concluded that their isolated plasmid # 319-13 contained the human fibroblast interferon gene, as opposed to some other gene:

It is important that in the sequence there exist without any errors the base sequence [three base pairs] corresponding to the amino acid sequence from the amino-terminal to 13th amino acid of the human fibroblast interferon reported by Knight, et al. [Science vol. 207, p. 525-526, (1980)]. *The fact proves that # 319-13 plasmid has the human fibroblast interferon mRNA sequence.* Further, it is apparent from the data of the primary sequence that the plasmid encompasses *the entire coding region of the protein* of the above mRNA and probably the coding region of the signal peptide.

(A306450, lines 1-11; emphasis added). Thus, Sugano used Knight’s 13-amino acid amino-terminal sequence (A300442, Fig. 3) to verify that the hFIF gene had, in fact, been cloned. However, the Japan application does not identify the 166

amino acids of mature hFIF nor disclose where the presequence ends or where the mature sequence begins.

In addition to lacking description of a molecule within the DNA count, the Japan application lacks any instructions that one should prepare such a DNA molecule, much less provides any description of *a method for making* a DNA molecule of the count. There are only three sentences of the Japan application that even purport to describe production of “interferon”:

The present inventors thought that it was the novel technique for producing *interferon* with ease and in a large quantity to insert a human interferon gene into a plasmid DNA (for instance plasmid DNA derived from Escherichia coli) with the recombinant DNA (deoxyribonucleic acid) technology. . . .

. . .

. . . . The aim of this invention is to provide novel recombinant plasmids which grow and amplify in bacteria such as Escherichia coli and, as a result, can be used to produce *human fibroblast interferon* in bacteria such as Escherichia coli.

(A306436, lines 6-23; italics added).

The *[sic]* supports that transformation of the plasmid or mRNA inserted therein to other expression plasmids enables a host such as Escherichia coli to produce *interferon*.

(A306450, lines 12-14; italics added).

None of these quotations identifies the structure of the “interferon” that would result from the undisclosed production method. The first and last quotation simply identify “interferon” with no structural description. The second quotation

mentions “human fibroblast interferon,” again with no explicit reference to structure, although the Board interpreted that term to mean the 187-amino acid hFIF precursor. (A000018, FF31).

Thus, the Japan application itself fails to describe a DNA required by the DNA count or mature hFIF polypeptide required by the protein count.

## **2. The Experts’ Views Of The Japan Application**

Sugano’s expert, Dr. Thomas Roberts, conceded that the Japan application “does not explicitly demarcate where the presequence ends and where the mature protein sequence begins.” (A306518-19, ¶44 n.1). He opined that, nevertheless, *one skilled in the art* would have understood that demarcation:

In view of Knight’s disclosure of the sequence of the N-terminal 13 amino acids of human fibroblast interferon, *a person of ordinary skill* in the field of recombinant DNA technology or bacterial protein expression as of March 19, 1980 would have immediately known the coding sequence for the mature human fibroblast interferon amino acid sequence given within the full-length cDNA sequence. Page 15 of the Japanese application lists the nucleotide sequence of the human fibroblast interferon cDNA and encoded amino acids. The amino acid sequence contains the leader or presequence of interferon as well as the mature protein sequence, *but does not explicitly demarcate where the presequence ends and where the mature protein sequence begins*. But in view of the Knight disclosures, *one of ordinary skill* would have immediately understood that the presequence consists of the first 21 amino acids because the Knight disclosures teach that the mature sequence begins with the amino acid sequence Met-Ser-Tyr-Asn-Leu-Leu-Gly-Phe-Leu-Gln-Arg-Ser-Ser . . . .

*Id.* (emphasis added). Later in his declaration, Dr. Roberts again stated that *a person of skill in the art* would have immediately known the starting amino acid of

mature hFIF. (A306559, ¶105; A306559-60, ¶106). However, the Japan application does not indicate the starting amino acid of mature hFIF.

Goeddel's expert, Dr. Rik Derynck, confirmed that the Japan application does not identify the 166 amino acids of mature hFIF or the 21-amino acid presequence:

The Japan '931 application notes the importance of the finding of the 13-amino acid sequence reported by Knight (Exhibit 1037 [A300440-42]) (Exhibit 2013, at 16, ll. 1-7 [A306450]) and then suggests that "the plasmid encompasses the entire coding region of the protein of the above mRNA and probably the coding region of the signal peptide" (Exhibit 2013, at 16, ll. 8-11 [A306450]). However, the Japan '931 application does not identify the reported 187-amino acid sequence as a precursor protein, *nor does this application identify either the 166-amino acid mature form of human fibroblast [interferon] nor the 21-amino acid signal peptide.*

(A301544, ¶157; emphasis added). Dr. Derynck characterized Sugano's Japan application as disclosing only a molecule containing DNA encoding the 166-amino acid sequence "embedded within" a larger DNA sequence encoding the 187-amino acid precursor, but without disclosing a stand-alone DNA molecule encoding mature hFIF unaccompanied by the hFIF presequence as required by the DNA count. (A301546, ¶163). Nor does it disclose a stand-alone polypeptide of the protein count. (A301546, ¶164). By definition, a DNA molecule encoding the 166-amino acid sequence is merely a portion of a DNA molecule encoding the hFIF precursor unless and until the covalent bonds attaching it to DNA encoding

the presequence are cleaved. Similarly, the 166-amino acid mature hFIF is merely a portion of the 187-amino acid precursor until the presequence is cleaved.

Despite that absence of any disclosure in the Japan application of a DNA molecule encoding mature hFIF unaccompanied by its presequence, Dr. Derynck addressed what *one skilled in the art* might have been able to “envision” from Table 5 of Sugano’s Japan application:

In view of the 13 amino-terminal amino acids of human fibroblast interferon disclosed by Knight (Exhibit 1037 [A300440-42]), *those of ordinary skill in the art* should have been able to envision a DNA encoding mature human fibroblast interferon having a total of 166 amino acids and unaccompanied by the human fibroblast interferon signal peptide (*e.g.*, a DNA consisting of base pairs 70-567 of the sequence provided at p. 15) (Exhibit 2013, at 15 [A306449]). *Sugano’s specification, however, did not do so.*

(A301545, ¶159; emphasis added).

Nevertheless, as Dr. Derynck so clearly stated, Sugano’s Japan application does not disclose such DNA molecules encoding mature hFIF unaccompanied by its presequence. Dr. Derynck ultimately concluded that Sugano had not demonstrated possession of a molecule of the DNA count:

In view of the information provided in the specification of the Japan ’931 application, one of ordinary skill in the art *would not have believed that*, as of March 19, 1980, *Sugano possessed* a DNA encoding mature human fibroblast interferon having a total of 166 amino acids unaccompanied by the human fibroblast interferon signal peptide.

(A301550, ¶180; emphasis added).



Dr. Derynck also described what is necessary to produce a mature hFIF unaccompanied by its presequence in bacteria:

To successfully produce a mature human fibroblast interferon free of its signal peptide, two key elements must be achieved: (a) DNA encoding the precursor form must be "tailored," or modified, to remove those codons encoding the entire signal peptide and (b) the ATG corresponding to the first amino acid of the mature form must be properly positioned with respect to bacterial expression control elements.

(A301538, ¶140).

Dr. Derynck further testified that the Japan application does not describe a method, or provide an example, of how to modify the DNA molecule encoding the 187-amino acid precursor to remove that part of the DNA molecule encoding the presequence or properly position the mature 166-amino acid sequence with respect to expression control elements:

Nowhere in the Japan '931 application does Sugano describe a method for tailoring the human fibroblast interferon gene, which encodes the amino acids of the signal peptide, to remove those codons encoding the entire signal peptide. Nor does the Japan '931 application describe a method for making an expression vector in which the ATG corresponding to the first amino acid of the mature form is properly positioned with respect to bacterial expression control elements such that it is capable of directing expression of a DNA encoding a mature human fibroblast interferon having a total of 166 amino acids and free of the fibroblast interferon signal peptide.

(A301538-39, ¶141). *See also* A301547, ¶¶166, 167; A301550, ¶179.

Dr. Derynck further stated that the Japan application does not even reference a method in the scientific or patent literature by which that portion of a DNA

molecule encoding the presequence could be removed from the portion encoding the mature hFIF:

The specification of the Japan '931 application *does not provide any reference to a method* for removing the coding sequence of the human fibroblast interferon signal peptide to provide a coding sequence for the mature form of human fibroblast interferon having a total of 166 amino acids unaccompanied by the human fibroblast interferon signal peptide. In fact, the specification of the Japan '931 application *does not provide any reference to a method* for removing the coding sequence of the signal peptide of any precursor protein, so as to provide a coding sequence for the mature form that protein.

(A301547, ¶168; emphasis added). *See also* A301545, ¶158.

In the absence of a description in Sugano's Japan application of a method to remove that portion of the DNA encoding the presequence from the larger DNA encoding the hFIF precursor, there can be no description of an enabling method for making a mature hFIF polypeptide unaccompanied by a hFIF presequence. That modified DNA is essential to expressing the polypeptide in bacteria. (A301538, ¶140; A301541, ¶146).

**E. Goeddel's September 1980 Application Disclosed And Claimed DNAs Encoding Mature hFIF Unaccompanied By Its Presequence And The 166-Amino Acid hFIF Polypeptide Itself**

In marked contrast to Sugano's Japan application, Goeddel's September 25, 1980 application disclosed several DNA molecules encoding a 166-amino acid mature hFIF unaccompanied by a hFIF presequence, as required by the DNA count. Two of such DNA molecules are depicted in Figure 6 of the application, namely

the “504” and “505” base pair (“bp”) DNAs. (A300636). A detailed description of the construction of the 504 bp DNA is provided in Figure 4 and the accompanying text. (A300634; A300620 (last ¶)). Two DNAs designated “pFIF $\textit{lac9}$ ” and “pFIF $\textit{trp69}$ ” are also depicted in Figure 6 and their construction is described the accompanying text. (A300636; A300621). Goeddel’s application, unlike Sugano’s application (see Section G, *infra*), explains that “[t]he full-length gene . . . would be tailored, using synthetic DNA, to eliminate any leader sequence. . .” (A300613 (last ¶)) and describes an extremely detailed multi-step procedure for “removing the signal peptide coding region” (A300620-21). In that application, again unlike Sugano’s Japan application, Goeddel expressly *claimed* a DNA molecule “encoding the amino acid sequence of mature fibroblast interferon so as to permit expression thereof essentially *unaccompanied by any corresponding presequence or portion thereof.*” (A300629, original claim 3).

Goeddel’s September 25, 1980 application also explicitly disclosed actual expression of a mature hFIF having a total of 165 or 166 amino acids and unaccompanied by a hFIF presequence, as required by the protein count, and demonstration that the polypeptide exhibits interferon activity. (A300621, line 39 to A300622). Finally, Goeddel’s application, unlike Sugano’s Japan application, expressly *claimed* a polypeptide of the protein count as a bacterial extract comprising a “polypeptide consisting essentially of the amino acid sequence of

mature fibroblast interferon unaccompanied by the corresponding presequence or any portion thereof.” (A300629, original claim 5).

Also on September 25, 1980, Goeddel published a paper detailing how to produce a mature hFIF unaccompanied by its presequence using DNAs encoding that mature polypeptide. (A300102-19).

**F. Sugano Alleges That Three Scientists Worked Seven Days A Week For Ten Weeks To Express Mature hFIF Unaccompanied By Its Presequence**

Sugano’s own testimony shows that this work needed to express mature hFIF unaccompanied by its presequence was far from routine. Sugano presented the uncorroborated testimony of Dr. Taniguchi in an attempt to show that he and two other prominent scientists had accomplished this task. All three worked seven days per week on constructing a plasmid allegedly capable of expressing mature hFIF unaccompanied by its presequence. (A307108, ¶17). It was not until ten weeks later, however, that Dr. Taniguchi allegedly obtained data from which he concluded that the bacterial expression product of a gene encoding mature hFIF unaccompanied by its presequence exhibited interferon activity. (A307109, ¶20).

Thus, at best, *if* Dr. Taniguchi is correct and *if* his activities were provable and corroborated, it took three prominent scientists working seven days per week for ten weeks to modify the DNA molecule encoding the hFIF precursor to code for a mature hFIF unaccompanied by its presequence and express a protein having

interferon activity in bacteria. Despite statements by Dr. Taniguchi that the protein produced was a mature hFIF having a total of 166 amino acids and unaccompanied by its presequence because the protein exhibited biological activity (*id.*), demonstration of interferon activity alone is insufficient to prove production of the mature protein since Dr. Taniguchi himself has reported that bacterially-produced hFIF proteins other than mature hFIF exhibit interferon activity, *e.g.*, the 187-amino acid precursor (A301049, lines 13-22). But regardless, unlike Goeddel's September 25, 1980 application, absolutely nothing in Sugano's Japan application describes a DNA molecule encoding mature hFIF unaccompanied by its presequence, much less explains the complex procedure necessary to construct it.

**G. The Disclosure And Claims Of Sugano's Later-Filed U.S. Applications**

It was not until after Goeddel's September 25, 1980 application and literature publication (A300102-19) that Sugano filed an application describing a mature hFIF unaccompanied by its presequence, as required by the protein count. In contrast to the Japan application, Sugano's subsequently-filed U.S. patent application No. 06/201,359, filed October 27, 1980, delineates in its Table 5 the exact amino acids of the presequence (marked -21 to -1) and the 166 amino acids (marked 1-166) of mature hFIF. (A300488). That is, it identifies precisely where the presequence ends and where the 166-amino acid sequence begins, *whereas the*

*Japan application does not.* (A000024, FF54). In addition, the October 27, 1980 application states that “[t]he DNA sequence permits prediction of the entire amino acid sequence for human fibroblast interferon (amino acids 1-166) and its putative signal peptide (amino acids -21 to -1) as shown in the line above the DNA sequences.” (A300490, col. 15, lines 1-5). *This information is not present in Sugano’s Japan application.* (A000024, FF55).

Even then, however, Sugano’s October 27, 1980 application contained no *claims* that encompass a DNA molecule encoding a mature hFIF *unaccompanied* by its presequence and no claims that encompass a mature hFIF *unaccompanied* by a hFIF presequence. (A305973, A306178 and A305974).

It was not until March 22, 1983—through an amendment—that Sugano added a claim that encompasses a DNA encoding a mature hFIF unaccompanied by its presequence. (A306148-53). Therefore, the earliest Sugano presented claims that encompass a DNA molecule encoding a mature hFIF unaccompanied by a hFIF presequence was March 22, 1983. This was not only long after the filing of the Japan application, but it was also two-and-a-half-years after Goeddel filed a patent application and published a paper demonstrating that he had constructed such DNA molecules and expressed from them a mature hFIF having a total of 165 or 166 amino acids. (A300102-19; A301526-28, ¶¶117-18).

Moreover, it was not until June 5, 1995, when Sugano filed application No. 08/463,757, that Sugano first added a claim to any hFIF polypeptide at all (A301018-19). One of those claims, claim 31, encompassed a mature hFIF having a total of 166 amino acids unaccompanied by a hFIF presequence. This first attempt by Sugano to claim a polypeptide recited in the protein count was made *fifteen years after Goeddel first claimed and published that subject matter* (A300629; A300102-19).

#### **H. The Board's Analysis Of The Parties' Motions**

##### **1. Grant Of Sugano's Motions For Benefit Of Its Japan Application**

In analyzing whether there was written description for compounds within the counts in Sugano's Japan application, the Board contrasted the disclosure of that application with that of Sugano's later-filed U.S. application, filed October 27, 1980, noting that the Japan application "does not indicate by numbering the first amino acid in the Table 5 amino acid sequence" and "does not contain the statement that 'the entire amino acid sequence for hFIF (amino acids 1-166) and its putative signal peptide (amino acids -21 to-1)' is shown in the DNA sequence at Table 5." (A000047, lines 5-12).

Despite that absence of any disclosure of where the presequence ends and the mature sequence begins, the Board found that the sequence of mature hFIF

would have been readily apparent *to one skilled in the art* from the Japan application, given Knight's earlier disclosure of the 13-amino acid sequence:

*The sequences of mature hFIF DNA or polypeptide are not explicitly disclosed. As Goeddel concedes, one skilled in the art, given the sequence of Table 5 and the amino acid sequence of Knight, "should have been able to envision a DNA encoding mature hFIF having a total of 166 amino acids and unaccompanied by the hFIF presequence."* (FF 44). We agree given that:

- (1) Table 5 disclosed the precursor sequence (FFs 53-55),
  - (2) Knight is discussed in the '931 JP application as disclosing the first 13 amino acids of mature hFIF (FFs 41 and 53-55), and
  - (3) Table 5 discloses the endpoint of hFIF (FFs 53-55)
- the amino acid *[sequence]* of, and DNA sequence encoding, mature hFIF would be readily apparent.

(A000047, line 17 to A000048, line 5; emphasis added).<sup>4</sup>

In evaluating enablement for compounds of the two counts, the Board stated:

The '931 JP application itself does not disclose in detail how to express mature hFIF in *E. coli*, which would include the step of making the DNA molecule needed to express mature hFIF. Thus, we find that the guidance provided by the '931 application is minimal. However, in evaluating whether sufficient enablement was provided we look not just to the '931 application itself but also to, *inter alia*, the level of skill in the art and the state of the art at the time of filing, i.e., 19 March 1980.

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<sup>4</sup> The statement of Dr. Derynck relied upon by the Board in this quotation (FF44) addressed Sugano's involved application, filed October 27, 1980. (A000022, lines 3-7). Dr. Derynck made a similar statement with respect to Sugano's Japan application, filed March 19, 1980. See A301545, ¶159; A000029-30, FF84.



(A000048, lines 6-12; underscoring added).

In holding that the application satisfied the requirement for a written description of a method for making, *i.e.*, enablement for, a compound of each count, the Board improperly took it upon itself to supplement the actual disclosure of the application with prior art references extrinsic to and not cited in the application, even though the application itself does not suggest the necessity for carrying out such methods and, in fact, teaches away from having to carry out such methods:

We determine that Sugano has established that methods were known at the relevant time for directly expressing proteins in *E. coli* and that one skilled in the art would have been able to express mature hFIF using techniques that were known in the art. Sugano has also established that one skilled in the art would have expected that these non-glycosylated proteins would obtain [*sic, exhibit*] at least some biological activity.

(A000048, lines 17-22).

The Board continued with reference to testimony of Sugano's experts:

Based on the testimony of Dr. Roberts and the testimony of Drs. Content and Lauer, and the publications pointed out to us, Sugano has set forth a *prima facie* case showing that it is entitled to benefit of the '931 JP application.

(A000048, line 22 to A000049, line 2). Following that quotation, the Board cited its finding of fact, FF71 (A000027), which adds the following citation to Dr. Roberts' declaration: "(Exh. 2016 at ¶¶46 and citing to ¶¶37-41)." There are ten references to methods cited in ¶¶37-41 of the Roberts declaration (A306515-17)

and many more cited in the Decision, yet not one of those references refers to expression of hFIF. Since there are no citations to any prior art references relating to expression of proteins in bacteria in the Japan application, *none of those relied upon by the Board is cited in the Japan application.*

The Board concluded that the Japan application contained a constructive reduction to practice of each count, and accorded Sugano benefit of the filing date of that application for both counts. (A000008, lines 3-5).

**2. Dismissal Of Goeddel's Motions For Unpatentability Of Sugano's Involved Claims In The DNA Interference**

In the DNA interference, with respect to Goeddel's three authorized and briefed motions attacking patentability of all of Sugano's involved patent claims, the Board concluded that "we need not decide those motions to complete our determination of priority." (A000053, line 18 to A000054, line 12). Goeddel's motions for unpatentability were dismissed without consideration on the merits. (A000054, lines 18-20; A000055, line 14).

**3. Entry Of Judgment Against Goeddel**

Since the Board accorded Sugano benefit of the March 19, 1980 filing date of the Japan application for both counts, and Goeddel's priority statements did not allege a date of invention prior to March 19, 1980, the Board awarded priority in both interferences to Sugano and entered final judgment against Goeddel. (A000055, lines 16-21).

## SUMMARY OF THE ARGUMENT

I. The Board erred as a matter of law in concluding that Sugano's Japan application contains a written description of a molecule within the DNA count and a polypeptide within the protein count. The Board erred in applying an improper legal standard, namely, whether *one skilled in the art* would have been able to "envision" a DNA molecule or polypeptide within the counts given the application, rather than whether one skilled in the art would have clearly concluded that the *inventors themselves* had described, *i.e.*, were in possession of, a DNA encoding mature hFIF unaccompanied by its presequence, or a mature hFIF unaccompanied by its presequence. The Board's analysis ignored (i) the inventors' many statements in the application itself that their invention was a DNA molecule encoding the *entire* 187-amino acid hFIF precursor and recombinant plasmids containing that DNA, and that those plasmids could be used to express an interferon of undefined structure and (ii) the inventors' statement that their invention was complete, despite the absence of any disclosure in the application that one must alter the DNA molecule encoding the 187-amino acid precursor to remove the DNA encoding the 21-amino acid presequence to achieve direct expression in bacteria of a mature hFIF unaccompanied by its presequence.

The process by which the Board evaluated the Japan application was thus seriously flawed. The Board began its analysis with a compound of each count and

then, working backward from the answer, tried to determine whether there was any basis in the application for envisioning that compound, rather than reviewing the application as a whole to determine what invention the inventors themselves described as their invention.

As a result of this legal error, there is no substantial evidence supporting the Board's finding that Sugano's Japan application contained a written description of a molecule within each count.

II. The Board erred as a matter of law in finding a written description of *a method for making a DNA molecule* of the DNA count and a *method for making a polypeptide* of the protein count, *i.e.*, enablement, solely based on methods that were not described or even cited to in the Japan application. Sugano's Japan application describes only a DNA molecule encoding the 187-amino acid hFIF precursor, and lacks any suggestion that one should modify that DNA molecule to remove the DNA encoding the 21-amino acid hFIF presequence to provide a DNA molecule encoding a mature hFIF having a total of 166 amino acids. Moreover, there is no teaching or description in the Japan application of any procedure for removing the DNA encoding the 21-amino acid presequence. This essential description must be in the Japan application itself in order for that application to be enabling. The absence of such essential description cannot be remedied by reliance on information in the art where, as here, there is no legally cognizable

motivation for one skilled in the art to look outside the application for references that could achieve that modification.

III. In the DNA interference, the Board abused its discretion by dismissing Goeddel's three motions attacking patentability of Sugano's claims. The only potentially relevant reasons given by the Board for exercising its discretion not to consider Goeddel's unpatentability motions are that (i) neither the motions individually or collectively attack all of Sugano's involved claims and (ii) Goeddel has an alternative remedy by reexamination, "at least as to the prior art challenges." However, the first is incorrect because one of Goeddel's motions *does* attack all of Sugano's involved claims. The second reason is insufficient since Goeddel's motion attacking all of Sugano's involved claims is based on 35 U.S.C. §§101 and 112 for lack of utility and a second Goeddel motion attacks Sugano's claims as unpatentable under 35 U.S.C. §101 over a product of nature, neither of which can be raised in a reexamination. Because none of these reasons survives scrutiny, the Board abused its discretion in not considering Goeddel's motions.

### **STANDARDS OF REVIEW**

This Court reviews the Board's legal conclusions *de novo* and the Board's factual findings to determine whether they are supported by substantial evidence. *In re Garner*, 508 F.3d 1376, 1378 (Fed. Cir. 2008).

Whether an application satisfies the written description requirement of 35 U.S.C. §112, first paragraph, is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1566 (Fed. Cir. 1991).

Whether an application is enabling is a legal conclusion based upon several underlying factual inquiries. *In re Wands*, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988).

Board decisions pursuant to the permissive rules governing patent interference proceedings are reviewed for abuse of discretion. *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004). Specifically, the Board's decision to terminate an interference once priority is determined, notwithstanding the pendency of unpatentability motions, is a matter of discretion. *Id.* at 1327.

## ARGUMENT

### **I. In Finding Written Description, The Board Improperly Relied On What One Skilled In The Art Might Have Been Able To Envision From Sugano's Application, Rather Than What The Inventors Themselves Described As Their Invention**

The Board erred as a matter of law in holding that Sugano's Japan application contained a written description based on what someone skilled in the art may have been able to envision from the application, where the application itself never mentioned or described the invention of either count and, in fact, expressly described the invention as something else. Although the known state of

the art can, in some circumstances, be used to explain the written description in a patent specification by filling in minor gaps, it cannot be used to change or supplant the description that is actually there. Sugano's Japan application described only DNA molecules encoding the 187-amino acid precursor, not DNA molecules encoding a 166-amino acid mature hFIF unaccompanied by its presequence and only the 187-amino acid precursor, not a 166-amino acid mature hFIF polypeptide. That failure to disclose a compound of each count cannot be rectified by after-the-fact speculation that one skilled in the art might have envisioned these compounds of the counts.

In order to be accorded benefit of an earlier-filed application for priority purposes, that application must contain a constructive reduction to practice of an embodiment within the count. *Frazer v. Schlegel*, 498 F.3d 1283, 1287 (Fed. Cir. 2007). The question is “whether *the document* discloses the invention of the count by meeting the written description and enablement requirements of 35 U.S.C. § 112 ¶1, for a filed application serves as a constructive reduction to practice of its content.” *Id.* (emphasis added).

To satisfy the written description requirement, an application must describe the invention such that a person skilled in the art would clearly conclude that *the applicants had invented* the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997); *Gentry Gallery, Inc. v. Berkline*

*Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

*Lockwood* discussed what does not suffice as a substitute for an express disclosure:

Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. . . . The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. See *Martin v. Mayer*, 823 F.2d 500, 504, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987) (stating that it is “not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure . . . . Rather, it is a question whether the application necessarily discloses that particular device.”).

*Lockwood*, 107 F.3d at 1571-72 (underscoring added).

In *Lockwood*, the district court held Lockwood’s ’355 patent invalid as anticipated under Section 102(b) by Lockwood’s ’359 patent, which had issued from the first application in a chain of five applications that ultimately issued as the ’355 patent. *Id.* at 1569. The district court found that the ’355 patent was not entitled to benefit of the filing date of the ’359 patent and, therefore, the ’359 patent anticipated because it issued over one year before the effective date of the ’355 patent claims. *Id.*



In order to obtain benefit of an earlier-filed application, each application in the chain must satisfy the written description requirement for the invention of Section 112. However, the district court found that two of the intervening applications in the chain failed to comply with the written description requirement for the '359 patent claims. *Id.* at 1571. On appeal, American argued that (i) one of the intervening applications failed to disclose a computer system connected to multiple vendors and (ii) another intervening application failed to disclose individual merchandizing apparatus that contained video disk players or other equivalent storage means, which features were recited in the claims. *Id.* at 1572. Lockwood presented expert testimony that (i) the former application disclosed a terminal that “can be connected” to multiple vendors and (ii) although the latter application only “discusses use of a television set and a keypad at a consumer’s home,” *it would have been apparent to one skilled in the art* that “Lockwood also envisioned the use of a terminal” containing a video disk player. *Id.*

This Court rejected that argument:

That does not solve Lockwood’s problem. . . . *It is not sufficient* for purposes of the written description requirement of § 112 *that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.* Each application in the chain must describe the claimed features. It is undisputed that one of the intervening applications does not describe an individual terminal containing a video disk player.

*Id.* (emphasis added). Thus, as a matter of law, the written description requirement is not satisfied by what a skilled artisan might have been able to “envision,” where the inventor himself “failed to disclose” such an invention.

Similarly, in *Gentry Gallery*, the patent described a sectional sofa with a center console including recliner controls. The specification clearly identified that center console as the only possible location of the controls. 134 F.3d at 1479. The patentee considered placement of the controls in the console “to be an essential element of his invention.” *Id.* This Court limited the scope of patentee’s permissible claims to a sofa with controls located in the center console because “[the patentee’s] original disclosure serves to limit the permissible breadth of his later-drafted claim.” *Id.*

**A. Sugano’s Inventors Repeatedly Characterized Their Invention As A DNA Molecule Encoding The 187-Amino Acid Precursor, *Not* A DNA Molecule Encoding The 166-Amino Acid Mature hFIF**

Repeatedly throughout the Japan application, the inventors characterized their invention as a novel recombinant plasmid having the hFIF messenger RNA gene, which encodes the 187-amino acid precursor form of hFIF, as shown in Table 5. (A306435-36; A306441). The inventors emphasized that their completed invention was directed to *the entire coding region* of the gene:

The present inventors thought that it was the novel technique for producing interferon with ease and in a large quantity to insert a human interferon gene into a plasmid DNA (for instance plasmid

DNA derived from Escherichia coli) with the recombinant DNA (deoxyribonucleic acid) technology. *The inventors have completed this invention* based on the thought.

That is, this invention relates to a novel recombinant plasmid, having a gene which encompasses at least *the entire coding region* of the human fibroblast interferon messenger RNA . . . .

. . .

“*The entire coding region*” means the part specifying the whole amino acid sequence of the protein of the human fibroblast interferon in the human *fibroblast interferon messenger RNA* sequence.

The novel recombinant plasmid (or recombinant plasmid DNA) having a gene which encompasses *the entire coding region* of the human fibroblast interferon messenger RNA has been obtained for the first time by the present inventors.

(A306436, lines 6-32; italics added).

It is clear from the inventors’ own statements that they considered their invention complete with the isolation and sequencing of a DNA molecule encoding *the entire human fibroblast interferon gene*, meaning a DNA molecule encoding the 187-amino acid precursor, and inserting that entire gene into a recombinant plasmid to allow production of “interferon.” Sugano’s inventors believed they had accomplished their goal, and yet *they never even mentioned* a DNA molecule encoding a mature hFIF having a total of 166 amino acids and unaccompanied by the hFIF presequence. Nor did they mention that modification of the DNA molecule encoding the hFIF precursor was necessary to achieve their goal of producing “interferon” in bacteria. Thus, they never described or even suggested

any modification of that DNA molecule to eliminate the portion encoding the presequence and, therefore, never described a DNA molecule encoding mature hFIF having a total of 166 amino acids and *unaccompanied* by the hFIF presequence. Indeed, it is not surprising that they did not suggest to modify the hFIF precursor DNA because they considered their invention complete upon obtaining a DNA molecule encoding the entire coding region of the 187-amino acid hFIF precursor and inserting it into a plasmid.

Sugano's passing reference to Knight's 13-amino acid sequence (A300442, Fig. 3) does not mean that Sugano disclosed a DNA molecule encoding a protein other than the 187-amino acid precursor or a hFIF polypeptide other than that precursor. Sugano merely referred to the Knight sequence to *verify* that the DNA molecule encoding the human fibroblast interferon gene had been obtained:

It is important that in the sequence there exist without any errors the base sequence [three base pairs] corresponding to the amino acid sequence from the amino-terminal to 13th amino acid of the human fibroblast interferon reported by Knight, et al. [Science vol. 207, p. 525-526, 1980]. *The fact proves that # 319-13 plasmid has the human fibroblast interferon mRNA sequence.* Further, it is apparent from the data of the primary sequence that the plasmid encompasses the entire coding region of the protein of the above mRNA and *probably* the coding region of the signal peptide.

(A306450, lines 1-11; emphasis added). Even though Sugano equivocally noted that the sequence included "probably the coding region of the sequence of the signal peptide," the inventors never identified where the signal peptide ends and

the mature sequence begins, or that the DNA encoding the signal peptide must be deleted from the hFIF gene.

Accordingly, the Japan application describes the completed invention as a DNA molecule encoding the 187-amino acid hFIF precursor. Neither a DNA molecule encoding the 166-amino acid mature hFIF unaccompanied by its presequence, nor a mature hFIF polypeptide unaccompanied by its presequence, is even mentioned in the disclosure.

**B. Instead Of Analyzing What Sugano Disclosed, The Board Improperly Focused On Whether One Skilled In The Art, Given The Counts In The Interferences, Could Envision A Compound Within Them**

The Board's analysis of Sugano's benefit motion never addressed the above-noted parts of the Japan application that describe Sugano's invention. (A000023, line 13 to A000032, line 19; A000045, line 21 to A000053, line 9). Rather, the Board immediately focused on the DNA sequence and deduced amino acid sequence of Table 5 to determine whether, given the counts, *one skilled in the art* would have been able to find within the sequence of Table 5 the sequences recited in the counts. (A000024, lines 1-8; A000047, line 1 to A000048, line 5).

The Board entirely ignored the rest of Sugano's specification that demonstrates what the inventors stated their invention was, namely, a DNA molecule encoding the 187-amino acid precursor, and inserting *that DNA* into a

plasmid to make the 187-amino acid “interferon” that would be expressed. They described their invention as complete, with no mention at all that one needed to or should remove the DNA encoding the 21-amino acid presequence to achieve production of the 166-amino acid mature hFIF unaccompanied by its presequence. This was, in fact, an affirmative teaching *away from* the inventions of the counts that cannot be ignored.

After acknowledging that neither a mature hFIF DNA molecule nor a mature hFIF unaccompanied by its presequence was explicitly disclosed, the Board focused on a purported “concession” by Goeddel’s expert, Dr. Derynck, which it then used as a “road map” for one of ordinary skill to find in Table 5 where the presequence ended and the mature sequence began:

*The sequences of mature hFIF DNA or polypeptide are not explicitly disclosed.* As Goeddel concedes, one skilled in the art, given the sequence of Table 5 and the amino acid sequence of Knight, “should have been able to envision a DNA encoding mature hFIF having a total of 166 amino acids and unaccompanied by the hFIF presequence.” (FF 44). We agree given that:

- (1) Table 5 disclosed the precursor sequence (FFs 53-55),
  - (2) Knight is discussed in the ’931 JP application as disclosing the first 13 amino acids of mature hFIF (FFs 41 and 53-55), and
  - (3) Table 5 discloses the endpoint of hFIF (FFs 53-55)
- the amino acid [*sic, sequence*] of, and DNA sequence encoding, mature hFIF would be readily apparent.

(A000047, line 17 to A000048, line 5; emphasis added).

The Board, however, did not quote the next sentence of Dr. Derynck's declaration regarding the Japan application, where he stated that although someone might have been able to "envision" a DNA molecule encoding mature hFIF unaccompanied by its presequence, "*Sugano's specification, however, did not do so.*" (A301545, ¶159; emphasis added). The Board thus approached the issue from the perspective of what *one skilled in the art* would have been able to find within the amino acid sequence of Table 5 when that sequence is considered together with the 13 amino-terminal amino acids of hFIF published by Knight. The Board, in effect, ignored the balance of the Japan application which describes what *the inventors* showed they had invented, namely, a DNA molecule encoding the 187-amino acid precursor. But it is the latter that is the only proper focus of the inquiry. *Lockwood*, 107 F.3d at 1571-72; *Noelle v. Lederman*, 355 F.3d 1343, 1348 (Fed. Cir. 2004); *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

Importantly, the purported "concession" of Goeddel's expert relied upon by the Board expressly addressed what *one skilled in the art* may have been able to "envision" from Table 5 given the Knight sequence. This, of course, does not reflect what *the inventors* believed their invention was, nor what they disclosed in the Japan application. Furthermore, the inventors themselves stated that they utilized Knight's 13-amino acid sequence merely *to confirm* that they had cloned

the hFIF gene (as opposed to some other gene), not to identify where the presequence ends and the mature sequence begins. Thus, the Board found that one skilled in the art would have drawn conclusions from Table 5 that the inventors themselves never disclosed in the application.

There is no evidence that one skilled in the art would have concluded that Sugano's inventors had invented a molecule within each count. Sugano's expert, Dr. Roberts, agreed that the Japan application "does not explicitly demarcate where the presequence ends and where the mature protein sequence begins." (A306518-19, ¶44 n.1). Nevertheless, he explained that *one skilled in the art* would have understood that demarcation (A306559-60, ¶¶105, 106), again not addressing what the *inventors themselves* had shown in their application that they had invented. Sugano never suggested anywhere in its Japan application that DNA encoding the signal peptide needed to be deleted to complete its invention.

It is also telling that Sugano amended Table 5 in its subsequently-filed United States application to show precisely where the presequence ends and the mature sequence begins. (A300488). Sugano also added in that application, filed October 27, 1980, explicit disclosure that amino acids 1-166 as newly labeled in Table 5 were the sequence of mature hFIF.

Sugano, however, never even presented a *claim* that encompassed a DNA encoding a mature hFIF unaccompanied by its presequence until over two years



after Goeddel filed its September 25, 1980 application claiming such a molecule. And, it was not until *fifteen years after* Goeddel filed that application that Sugano presented a claim that encompassed a mature hFIF polypeptide. Clearly, Sugano did not consider the 165- or 166-amino acid mature hFIF or a DNA encoding that polypeptide to be its invention until very late in the game.

Finally, Goeddel's expert, Dr. Derynck, characterized Sugano's Japan application as disclosing a DNA sequence encoding the 166-amino acid sequence only as "embedded within" the larger DNA sequence encoding the 187-amino acid precursor (A301546, ¶¶163, 164), not as an independent, stand-alone DNA molecule encoding a 166-amino acid hFIF *unaccompanied* by the 21-amino acid presequence, *as required by the DNA count*. It is important to realize here that the invention of the DNA count is a chemical *compound, i.e., a DNA molecule*. The structure of that DNA molecule is described in terms of the *sequence* of nucleotides that make up that molecule. Thus, there is a critical distinction between the DNA *sequence*, which is information describing the molecule, and the *DNA molecule itself*, which is a physical object. One may, for example, know the DNA sequence yet not have, nor know how to make, a physical embodiment of the DNA molecule of the DNA count.

Similarly, the Japan application discloses the 165- or 166-amino acid hFIF sequence *only* as "embedded within" the larger 187-amino acid sequence of the

hFIF precursor, not as an independent polypeptide unaccompanied by the 21-amino acid presequence, as required by the protein count.

The application shows that the only DNA molecules Sugano possessed were those in which DNA encoding the 166-amino acid hFIF sequence is covalently attached to DNA encoding the presequence, for example, plasmid # 319-13. The application does not show that Sugano possessed as his invention a DNA molecule encoding mature hFIF without the nucleotides encoding the presequence covalently attached. Thus, Sugano did not show possession in its Japan application of a DNA molecule within the DNA count; at best, Sugano described the sequence of such DNA molecule, though only as a subsequence of, or embedded within, a larger DNA sequence and accompanied by DNA encoding the presequence. That is quite different from what is required by the DNA count.

Similarly, Sugano did not show possession in its Japan application of a 165- or 166-amino acid polypeptide having the sequence of mature hFIF unaccompanied by a hFIF presequence, as explicitly required by the protein count.

The law of written description requires that the Japan application precisely describe a DNA molecule encoding mature hFIF having a total of 166 amino acids and unaccompanied by the 21-amino acid hFIF presequence, and a mature hFIF polypeptide unaccompanied by its presequence, in sufficient detail such that one skilled in the art can clearly conclude that Sugano's inventors were in possession

of those inventions as of the filing date. The Board concluded, however, that such compounds would have been *apparent to one skilled in the art* given the Japan application and the Knight publication, not that one skilled in the art could have clearly concluded that *Sugano's inventors themselves* described them in the application. One of ordinary skill in the art would not have been convinced that Sugano had either invented or possessed a DNA molecule of the DNA count or a polypeptide of the protein count as of March 19, 1980. (A301550, ¶180). The Japan application itself simply does not describe a DNA molecule encoding mature hFIF having a total of 166 amino acids *unaccompanied* by the hFIF presequence, or the encoded mature hFIF. (A301546, ¶¶163, 164).

In summary, the Japan application lacked a disclosure of an embodiment within each count, *i.e.*, a mature hFIF unaccompanied by its presequence or a DNA encoding that protein, a fact that was supported by substantial evidence: (i) Sugano's inventors described their invention only as the full sequence of the hFIF gene (which encodes the 187-amino acid precursor) and never themselves described DNA encoding the 166-amino acid mature hFIF as their invention, (ii) Sugano's expert conceded that mature hFIF was not disclosed in the Japan application but opined that one skilled in the art could figure it out and (iii) Goeddel's expert agreed that one skilled in the art might have been able to envision mature hFIF when combining the Japan application together with the

Knight publication, but Sugano's inventors did not do that in the Japan application. Remarkably, although the Board itself found that mature hFIF is not explicitly disclosed, it erred as a matter of law in relying on what one skilled in the art could "envision" to make up for the lack of written description in the Japan application.

*Lockwood* cautioned that a written description cannot be based on what "could have been done" with an applicant's disclosure, or what would have been apparent *to one skilled in the art* given that disclosure. The evaluation must focus on whether the *inventors themselves* actually invented the subject matter of the claim or count. 107 F.3d at 1572. Moreover, *Gentry Gallery* shows that an original disclosure serves to limit the scope of later-filed, permissible claims to that disclosure. 134 F.3d at 1479. In this case, the Board failed to follow these teachings. There is simply no evidence that one skilled in the art would have concluded from the Japan application that Sugano's inventors had possessed the compounds of either count. Accordingly, this Court should reverse the Board's decision according Sugano benefit of the Japan application.

**II. The Board Improperly Based Its Finding Of Enablement Solely On Prior Art References Not Cited In The Japan Application, Rather Than On The Disclosure Of The Japan Application Itself**

As confirmed by this Court, Section 112 sets forth dual requirements for written description:

The “written description” clause of section 112 has been construed to mandate that the specification satisfy two closely related requirements. First, *it must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation. . . .* Second, it must *describe the invention* sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed.

*Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005) (emphasis added). *See also In re Barker*, 559 F.2d 588, 593 (C.C.P.A. 1977). Thus, Section 112 requires both (i) a *written description* of the invention and (ii) a *written description* of how to make and use that invention. The latter is commonly referred to as the “enablement” requirement.

Enablement requires that a person skilled in the art be able to practice the invention without undue experimentation. *See, e.g., Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987). A number of factors have been considered in determining what constitutes undue experimentation, including lack of direction or guidance in the application. *In re Wands*, 858 F.2d at 737 (footnote omitted). An application may be found non-enabling based solely on lack of direction or guidance presented in the application itself. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997).

Where, as here, the claimed invention is a specific DNA molecule or requires a specific polypeptide, the written description requirement requires disclosure of a method of making that DNA molecule or polypeptide in sufficient detail that one skilled in the art would be convinced that the inventor *possessed* that DNA molecule or polypeptide as of the effective filing date. This is so because one cannot *describe* an invention that had not been conceived (*Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)), and conception of a DNA molecule requires *possession of both* (i) the idea of its structure *and* (ii) a method of making it. *Oka v. Youssefyeh*, 849 F.2d 581, 584 (Fed. Cir. 1988). The same is true for a polypeptide.

In *Genentech*, this Court noted that, while not every detail necessary to make the invention need be disclosed to meet the enablement requirement, an inventor cannot simply rely on what one skilled in the art could do:

It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, *when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required*; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. *It is the specification, not the knowledge of one skilled in the art, that must*

*supply the novel aspects of the invention in order to constitute adequate enablement.*

108 F.3d at 1366 (emphasis added). Thus, a defective application that fails to describe how to make the claimed invention cannot be remedied by reference to methods known in the art. *A written description of an enabling method of making the invention must be in the application itself. See also Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322-23 (Fed. Cir. 2005). The knowledge of one skilled in the art can be used to “fill in the gaps” in the description of the invention, but it cannot be used to supplant or supply the metes and bounds of the inventor’s actual invention as the inventor himself described it.

Genentech had claimed a method for expressing mature human growth hormone (“hGH”) using “cleavable fusion expression.” This Court found that Genentech’s patent “does not describe in any detail whatsoever how to make hGH using cleavable fusion expression.” 108 F.3d at 1365. “The specification does not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work.” *Id.* Novo argued “that the mere generic statement of the possibility of cleavable fusion expression, along with the DNA sequence encoding hGH, a single enzyme (trypsin) for cleaving undisclosed conjugate proteins, and a statement of that enzyme’s cleavage sites as being potential amino acid extensions conjugated to hGH is not an enabling disclosure.”

*Id.* at 1364. Genentech argued “that those skilled in the art of recombinant protein expression and purification at the time of filing . . . would have been able to use cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the *specification* along with methods and tools well known in the art.” *Id.*

This Court rejected Genentech’s argument that the knowledge of one skilled in the art was sufficient to provide all the missing information, despite that Genentech’s expert pointed to extensive description of enzymes in a reference textbook and to the application’s explicit reference to a British patent that discusses the potential use of trypsin in cleavable fusion expression. *Id.* at 1365.

This Court considered Genentech’s specification, which disclosed far more about cleavable fusion expression than Sugano’s Japan application discloses about modifying DNA molecule encoding a precursor protein to remove DNA encoding the presequence, and rejected Genentech’s arguments because they focused almost exclusively on the level of skill in the art and “ignor[ed] the essence of the enablement requirement.” *Id.* at 1366.

This Court’s legal analysis in *Genentech* did not depend on the claimed invention being a method. Whether the claim is to a compound or a method of making that compound, an enabling disclosure must teach how to make the compound. Moreover, this Court subsequently applied its analysis in *Genentech* to



a claim drawn to a mechanical device, *i.e.*, a claim not directed to a method. *Auto. Tech. Int'l v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283-84 (Fed. Cir. 2007). This Court cited to the analysis in *Genentech*, following which it stated: “Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention *must be enabled in the patent*. *Id.* at 1283 (emphasis added).

**A. There Is No Disclosure In The Japan Application Of Any Method To Make A DNA Molecule Encoding The 166-Amino Acid Mature hFIF Unaccompanied By Its Presequence, Or The Encoded Mature Polypeptide**

In the Japan application, there are only three sentences that even allude to making any “interferon” from any of the DNA molecules described therein:

The present inventors thought that it was the novel technique for producing *interferon* with ease and in a large quantity to insert a human interferon gene into a plasmid DNA (for instance plasmid DNA derived from Escherichia coli) with the recombinant DNA (deoxyribonucleic acid) technology. . . .

. . .

. . . . The aim of this invention is to provide novel recombinant plasmids which grow and amplify in bacteria such as Escherichia coli and, as a result, can be used to produce *human fibroblast interferon* in bacteria such as Escherichia coli.

(A306436, lines 6-11 and 19-23; italics added).

The [*sic*] supports that transformation of the plasmid or mRNA inserted therein to other expression plasmids enables a host such as Escherichia coli to produce *interferon*.

(A306450, lines 12-14; italics added).

None of these passages describes how to make a plasmid capable of expressing any protein from the DNA molecules disclosed. The first and last passages never characterize *what protein* is made—there is no description of the structure of the protein allegedly expressed. The middle passage purports to describe production of “human fibroblast interferon,” which the Board interpreted to mean the 187-amino acid hFIF precursor. (A000018, FF31).

Dr. Derynck, Goeddel’s expert, testified that in order to produce a mature hFIF having a total of 166 amino acids and unaccompanied by a hFIF presequence, one must achieve two milestones: (i) modify (or, as colloquially described, “tailor”) a DNA molecule encoding the 187-amino acid hFIF precursor to remove the DNA encoding the 21-amino acid presequence and (ii) properly position the ATG codon representing the first amino acid of mature hFIF with respect to bacterial expression control elements. (A301538, ¶140). He further testified that there is no description or example in the Japan application of a method for modifying the DNA molecule encoding the hFIF precursor to remove the DNA encoding the presequence. (A301538-39, ¶141; A301547, ¶¶166, 167). Similarly, Dr. Derynck testified that the Japan application lacks any reference to a method for removing the DNA encoding the presequence of *any* precursor protein to provide a DNA encoding the mature form of that protein, much less the 187-amino acid hFIF precursor. (A301547, ¶168; A301545, ¶158). This is in stark contrast to

Goeddel's September 25, 1980 application, which described in detail how to modify the precursor in order to produce mature hFIF. *See* Statement of the Facts, Section E, *supra*.

Thus, there is nothing at all in the Japan application showing how to make a DNA molecule of the DNA count, nor is there any direction to look to the literature of any method for making that compound. Since there is no disclosure of a DNA molecule encoding mature hFIF unaccompanied by its presequence, which is required for bacterial expression of the mature hFIF polypeptide, there is no description of a method for making the polypeptide of the protein count either. This failure to provide an enabling disclosure is far more apparent in this case than it was in *Genentech*.

**B. The Board Improperly Relied Solely On Methods In The Prior Art, But Not Disclosed In The Japan Application, To Find Enablement**

The Board's decision on enablement rested solely on prior art extrinsic to the application that was not even cited in the application. The Board noted that the Japan application "does not disclose *in detail* how to express mature hFIF," which includes the step of making the modified DNA molecule needed, and that the guidance in the application is "minimal."

The '931 JP application itself does not disclose in detail how to express mature hFIF in *E. coli*, which would include a step of making the DNA molecule needed to express mature hFIF. Thus, we find that

the guidance provided by the '931 application is minimal. However, in evaluating whether sufficient enablement was provided we look not just to the '931 application itself but also to, *inter alia*, the level of skill in the art and the state of the art at the time of filing, i.e., 19 March 1980. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) . . . .

(A000048, lines 6-12; underscoring added) While leaving the implication that there was *some* disclosure how to express mature hFIF (“does not disclose *in detail*”), the Board did not point to any part of the disclosure where any such information can be found. “Minimal” guidance is an overstatement; there is no guidance whatsoever.

The Board then looked to the level of skill in the art and the state of the art and cited to the many references relied upon in the declarations of Sugano’s experts (A000048, line 22 to A000049, line 26). None of those references, however, was cited in the Japan application; indeed, *there are no citations whatsoever* in the application to *any* references relating to expression of *any* proteins in bacteria.

Under the circumstances of this case, where there is no disclosure in the application of any method to express any protein in bacteria, no disclosure how to make a DNA molecule essential to such expression and no citation to any such methods in the prior art, the Board committed legal error in relying entirely on that information in the prior art. This is not a case where one skilled in the art would

know how to make the compound merely from knowing its structure, and where “textbook” organic chemistry showed how to make compounds of the class claimed. *Martin v. Johnson*, 454 F.2d 746, 749 (C.C.P.A. 1972).

Here, Sugano has admitted that it took over ten weeks effort by three prominent scientists working seven days a week to modify the DNA molecule encoding the hFIF precursor and demonstrate expression of an allegedly biologically active interferon protein.<sup>5</sup> Specifically, Sugano asserts that as of February 27, 1980, when Dr. Taniguchi arrived in their laboratory, Drs. Roberts and Guarente “had already begun preparing expression plasmids . . . .” (A307108, ¶17). According to Dr. Taniguchi, he believed that as of May 10, 1980, he had demonstrated expression of interferon activity from bacterial extracts. (A307109, ¶20). If all that were true, and provable, and corroborated, that would be over ten weeks effort by at least three highly trained scientists to make a DNA molecule of the DNA count. That is clearly more effort than was involved in *Martin*.

For all of these reasons, the Board erred as a matter of law in relying entirely on prior art references that are extrinsic to the Japan application, and not cited in the application, to satisfy enablement for the DNA count and the protein count. That decision should be reversed.

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<sup>5</sup> Goeddel’s reliance on Sugano’s subjective belief that mature hFIF was expressed does not constitute an admission that Sugano has proved an actual reduction to practice of the protein count.

### **III. The Board Abused Its Discretion In the DNA Interference In Dismissing Goeddel's Unpatentability Motions**

#### **A. The Board Had Authority To Decide Goeddel's Unpatentability Motions**

As early as *Perkins v. Kwon*, 886 F.2d 325 (Fed. Cir. 1989), this Court addressed the Board's authority to decide priority and patentability issues in situations where one party is not entitled to its claims in an interference. In 2002, reviewing *Perkins* and its several progeny, this Court confirmed the Board's authority:

those cases stand for the proposition that if, in a properly declared interference, an issue of priority or patentability is fairly raised and fully developed on the record, then the Board has the *authority* to consider that issue even after the Board determines that one party is not entitled to its claims.

*Berman v. Housey*, 291 F.3d 1345, 1352 (Fed. Cir. 2002) (emphasis in original).

*Berman* involved a motion by Housey for failure to satisfy 35 U.S.C. §135(b), which the Court characterized as a "threshold issue," which, if not satisfied, would deprive the Board of authority to continue the interference. *Id.* at 1351. Thus, the Court affirmed the Board's dismissal of Berman's unpatentability motions once it concluded that Berman failed to satisfy Section 135(b). *Id.* That limitation on the Board's authority, however, applies only to threshold issues, such as no interference-in-fact, repose under Section 135(b) and lack of written description for a claim copied from a patent. 37 C.F.R. §41.201.

In this case, after according Sugano benefit of the Japan application, and in view of Goeddel's priority statement, the Board concluded that Goeddel could not prevail on the issue of priority. (A00008, lines 3-8; A000053, lines 11-14). Because the Board's grant of priority to Sugano is not a threshold issue, the Board retained authority to decide Goeddel's unpatentability motions.

**B. The Board Abused Its Discretion In Dismissing Goeddel's Unpatentability Motions Without Consideration On the Merits**

The Board's decision refusing to consider Goeddel's unpatentability motions was an abuse of discretion because it "rests on clearly erroneous fact findings . . . and a record that contains no evidence on which the Board could rationally base its decision." *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050-51 (Fed. Cir. 1994).

The Board gave four reasons to justify exercising its discretion not to decide Goeddel's three unpatentability motions:

(1) neither any motion individually, nor the combination of the motions, attack the patentability of all of the involved Sugano claims in either interference. Thus, even if we granted each Goeddel motion attacking patentability, Sugano would have claims directed to mature hFIF and encoding DNA remaining in the interference,

(2) a decision on the patentability of the attacked Sugano claims is not necessary to a determination of priority,

(3) the Sugano claims that Goeddel contends are unpatentable are not part of the substitute Count of either interference and thus deciding the patentability motions could not have had the effect of changing the Count,

(4) in interference 105,334, at least as to the prior art challenges, Goeddel has an alternative remedy under 35 USC § 302 . . . .

(A000053, line 18 to A000054, line 12). None of these reasons justifies dismissal of Goeddel's motions.

The first reason is based on a clearly erroneous fact finding and, thus, is an abuse of discretion because Goeddel's motion attacking patentability of Sugano's claims for lack of utility addressed *all* of Sugano's involved claims. That is evident from the first sentence of the motion itself, which lists all of Sugano's involved claims as attacked by the motion. (A001554).

The second reason given by the Board is merely a restatement of accepted law with regard to patentability issues (other than threshold issues), since a party can prevail on priority regardless of whether its claims are patentable over prior art. *Perkins*, 886 F.2d at 325. This is not a rational basis for the Board's refusal to consider Goeddel's unpatentability motions and hence is an abuse of discretion. For while it is true that a decision on patentability is not necessary to a decision on priority, that fact does not absolve the Board of the need to consider patentability issues that are squarely put before it. In *Perkins*, this Court held that "Congress intended that if patentability is fairly placed at issue in [an interference] proceeding, it will be determined." *Id.* at 328. The Court further stated that "[t]o do otherwise



is contrary to the PTO's mission to grant presumptively valid patents, 35 U.S.C. Sec. 282, and thus disserves the public interest." *Id.* at 328-29.

The third reason—that no challenged Sugano claim forms part of count 2—while correct, is irrelevant. While it is true that the Board must consider a motion attacking patentability of a claim that forms part of a count, it is not required that an unpatentability motion attack claims that form part of the count in order to be considered. Thus, the Board's third reason does not rationally support dismissing Goeddel's unpatentability motions, and is an abuse of discretion.

The fourth reason, that Goeddel has an alternative remedy by way of reexamination "at least as to the prior art challenges," again while correct, is not a rational basis for dismissing Goeddel's motions. Two of Goeddel's motions, including the motion attacking all of Sugano's involved claims, are not based on prior art challenges. Neither Goeddel's motion attacking Sugano's claims for lack of utility (A001551-90) nor its motion attacking Sugano's claims as unpatentable for reading on a product of nature (A001294-335) raises issues that may be addressed in a reexamination. Thus, Goeddel does *not* have a remedy by way of reexamination and this rationale by the Board is likewise an abuse of discretion. And even as to prior art challenges, as explained above, the Court's decision in *Perkins* rested on Congress's preference that patentability issues be decided in interference proceedings whenever they are properly raised.

Each of the reasons given by the Board for refusing to consider Goeddel's unpatentability motions either rests on clearly erroneous fact findings or provides no rational basis for the Board's decision. *Abrutyn*, 15 F.3d at 1050-51. The Board abused its discretion in not considering Goeddel's motions.

Thus, independent of this Court's decision on Sugano's entitlement to be accorded the priority date of its Japan application (issues 1 and 2, *supra*), Goeddel requests that the Board be instructed to decide Goeddel's three unpatentability motions in the DNA interference.

### CONCLUSION

The Board's grant of Sugano's motions to be accorded benefit of the Japan application for both the DNA count and the protein count should be reversed, its judgments awarding priority of invention to Sugano should be vacated, Goeddel should be awarded senior party status and the interferences should be remanded to the Board for further proceedings.<sup>6</sup> Whether or not this Court reverses the Board's grant of Sugano's motion to be accorded benefit, the Board should be instructed to

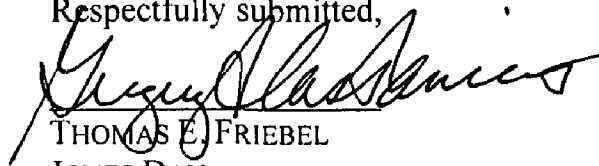
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<sup>6</sup> Upon remand, Goeddel intends to request, in each interference, briefing and decision on two additional Goeddel motions for unpatentability and a motion for priority that were authorized but deferred to the priority phase.

decide Goeddel's three unpatentability motions on the merits.

April 15, 2009

Respectfully submitted,



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## **ADDENDUM**

### **Interference 105,334:**

Judgment (Entered September 29, 2008)	A000001 – 03
Decision (September 29, 2008)	A000004 – 57
Redeclaration (September 29, 2008)	A000058 – 60
Notice of Appeal (w/o exhibits)	A000121 – 123

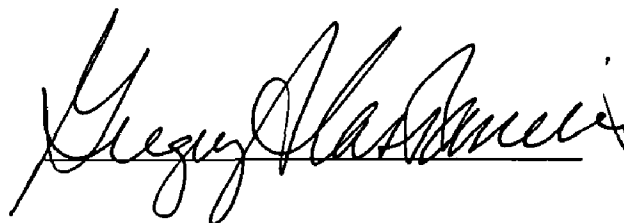
### **Interference 105,337:**

Judgment (Entered September 29, 2008)	A000061 – 63
Decision (September 29, 2008)	A000064 – 117
Redeclaration (September 29, 2008)	A000118 – 120
Notice of Appeal (w/o exhibits)	A000187 – 189

# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true copy of BRIEF OF APPELLANTS GOEDDEL was served this 15<sup>th</sup> day of April, 2009, by UPS Overnight as follows:

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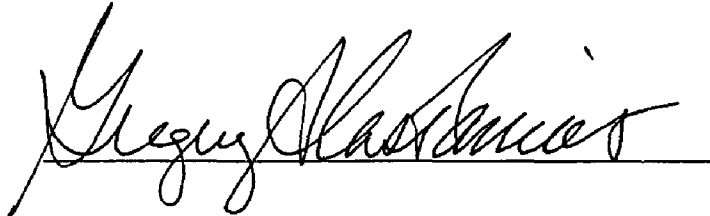
**CERTIFICATE OF COMPLIANCE**

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned certified that this brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b), this brief includes 13,998 words.

2. This brief has been prepared in proportionally spaced typeface Microsoft Word 2003 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count of this word-processing system in preparing this certificate.

Dated: April 15, 2009

A handwritten signature in black ink, appearing to read "Gregory K. Adams", is written over a horizontal line.